SERVICE MANUAL

Galaxy™ and Galaxy™2 Intravascular Ultrasound Systems

Boston Scientific

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Boston Scientific
Equipment Service Business

Service Philosophy

- Provide the customer with the highest quality service utilizing a team of dedicated, competent, well trained and well supported personnel.

- Respond to all customer requests in the most expeditious manner, which is mutually beneficial to the customer and Boston Scientific.

- Establish and maintain positive, long-term partnerships with all customers of Boston Scientific Corporation.

Service Policy

- The primary objective of the Equipment Service Business is to provide customers with a level of service and responsiveness that allows maximum system utilization.

- Products shall be serviced at the customer site or returned to Boston Scientific for servicing as required. When necessary an exchange or replacement item/unit may be provided to the customer, during (or instead of) factory repairs. Boston Scientific, or properly trained personnel, shall perform all Services.

- Boston Scientific Equipment Service Business provides the training, tools, and service necessary to achieve this result. The company provides support by the following methods:

Warranty Service

Warranty service is generally provided for:

- One year, instrument – new

- Ninety (90) days, replacement items

Note: Please refer to specific Warranty information in your Galaxy™ or Galaxy™2 User's Guide and/or your Boston Scientific Sales Agreement. Also reference Warranty information described in Chapter 1 of this Service Manual.

Service Agreement

A Service Agreement can be purchased at any time subject to verification of current system condition. This contract shall remain in effect for a minimum of one year and a maximum of five years. Service Agreements will offer a range of services and support levels.

Non-Warranty / Non-Contract

Boston Scientific will provide Non-Warranty / Non-Contract service to all domestic customers at an hourly rate, plus travel expenses and replacement parts costs.

Technical Support

Boston Scientific Customer Support will provide telephone assistance, where technical support is readily available; 5:30am to 5:00pm Pacific Time, Monday through Friday, excluding all holidays observed by Boston Scientific.

Emergency technical support is always available 24 hours/day, 7 days/week.

EMAIL: ivus.techsupport@bsci.com

PHONE: AT&T (800) 949-6708

Note: Basic Biomedical Equipment Technician training may be available for the Galaxy™ System. Contact Boston Scientific for more information.

Note: For clinical support (how to use your system), contact your local Boston Scientific Sales Representative.

Chapter 1 About This Manual

Service Manual Scope and Purpose

The Primary user of this documentation will be either a trained or untrained hospital Biomedical Equipment Technician (BMET) or similarly qualified service personnel. Please contact Boston Scientific for more information. A secondary user will be a trained Boston Scientific Field Service Engineer (FSE). Boston Scientific FSE's are trained to specific internal procedures, which includes but is not limited to, the entire contents of this manual.

This document is intended to provide information sufficient for a hospital BMET to provide proper equipment care, configure pre-sets, and perform basic preventative & corrective maintenance.

It is assumed the user of this manual can operate the System sufficiently to determine that it is functioning properly. This manual is intended to provide limited operating instructions for qualified operators, service personnel and technicians. This manual does not replace the User's Guide and is not meant to be a source of clinical information.

Galaxy™ and Galaxy™2

This manual includes information for both **Galaxy™** and **Galaxy™2** Intravascular Ultrasound Systems (IVUS).

Galaxy™ and **Galaxy™2** instrument functions are virtually the same. Differences between the two instruments are hardware related. For example, **Galaxy™** has a CRT monitor and **Galaxy™2** has a LCD display. **Galaxy™** has a CD-R and **Galaxy™2** has a DVD+RW. Please refer to Chapter 2, **Specifications** and Chapter 4, **Functional Description** for more specific details.

For the purposes of this service manual, these two instruments shall be defined and referenced throughout as follows:

Galaxy™	pertains only to software version 1.03 and lower
Galaxy™2	pertains only to software versions 2.01 & 2.02
Galaxy™ System	pertains to both **Galaxy™** and **Galaxy™2** as defined herein

The software version may be identified in the Imaging Menu.
Refer to the User's Guide for more information.

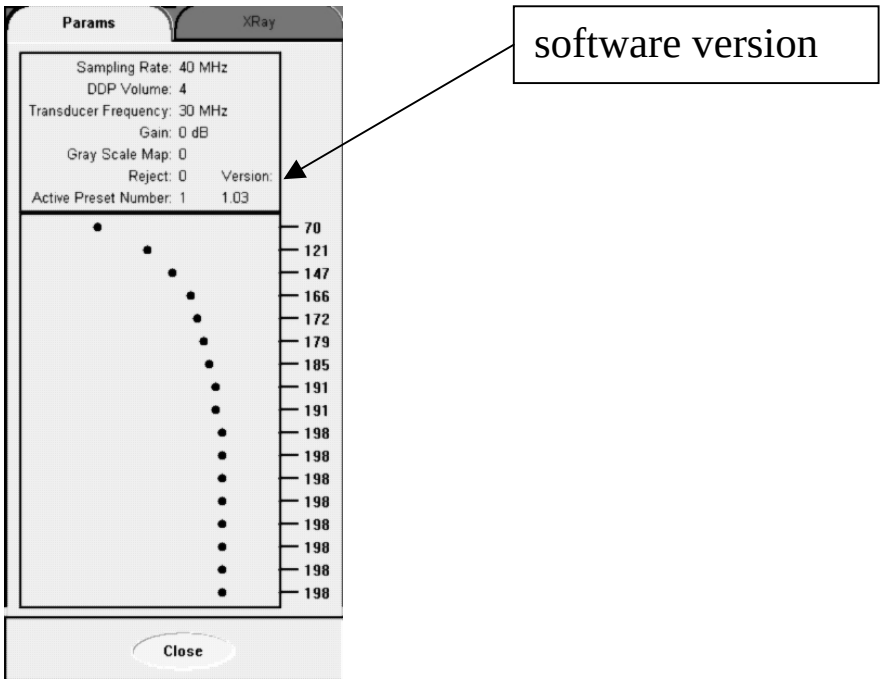


Figure 1 Viewing the software version in the Imaging menu

This manual covers the following areas:

Chapter 1: About This Manual - Provides warnings and general information regarding the contents of this manual.

Chapter 2: Galaxy™ System Specifications - Provides electrical, connection, physical and environmental specifications.

Chapter 3: Introduction to the Galaxy™ System - This chapter explains the capabilities and uses of the **Galaxy™ System**. It includes important information on the **Galaxy™ System's** unique features. This chapter is introductory in nature and intended to provide service technicians with a broad overview of the **Galaxy™ System**. Please refer to the **Galaxy™** or **Galaxy™²** User's Guide for more specific details regarding system operation.

Chapter 4: Functional Description - This chapter provides basic functional descriptions of **Galaxy™** and **Galaxy™²** components and their interrelationship so that operating principles may be understood.

Chapter 5: Galaxy™ System Maintenance - This chapter provides information on maintenance activities that can be performed by the end-user or technical maintenance personnel. It includes information on basic care of the **Galaxy™ System**, storage, cleaning, replacing fuses, considerations when relocating the **Galaxy™ System**, and problem solving.

Chapter 6: DICOM - This chapter is divided into two sections; DICOM configuration and DICOM usage/operation.

- DICOM Configuration: This section provides instructions for configuring the DICOM feature for **Galaxy™** running software version 1.03, or any **Galaxy™²**.
- DICOM settings and operation: These sections describe; 1) the user's default settings and manner in which the **Galaxy™ System** handles DICOM operations 2) **Galaxy™ System** DICOM operation.

Chapter 7: Overhead Monitor Switchbox (OMS) - This chapter provides technical information for understanding the operation and installation requirements for integrating the **Galaxy™ System** IVUS Imaging Overhead Monitor Switchbox (OMS) with Cath Lab x-ray systems. This chapter contains:

- description of OMS system operation
- overview of the installation process
- wiring diagrams and schematics
- frequently asked questions

Chapter 8: Galaxy™ System Parts Replacement - This chapter provides instruction for removing and replacing the internal subassembly components of the **Galaxy™ System**. These procedures are intended for field service engineers and biomedical equipment technicians.

Chapter 9: Parts - This chapter provides an itemized list of **Galaxy™ System** parts, accessories and ordering information.

Chapter 10: Diagrams – This chapter provides mechanical breakdown schematics, wiring and interconnection diagrams for troubleshooting purposes.

Overview

Most service support requirements that occur during the first year of ownership of the **Galaxy™ System** are covered by the warranty, as explained in the following sections. For support not covered under the terms of the warranty, Boston Scientific Corporation offers support on a per-call basis. Please contact the Boston Scientific Equipment Service Business at 1-800-949-6708 for equipment support for your **Galaxy™ System**, or for information on available service support programs.

Warranty Information

Boston Scientific Corporation warrants that reasonable care has been used in the design and manufacture of the **Galaxy™ System**. When maintained in such conditions as specified by Boston Scientific Corporation, it will be free from defects in material and workmanship at the buyer's location for 12 months from the date of delivery (unless a shorter period for a specific component is specified). This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law, or otherwise including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning, and sterilization of this instrument, as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Boston Scientific Corporation's control directly affect the instrument and the results obtained from its use. Boston Scientific Corporation's obligation under this warranty is limited to the repair or replacement of this instrument, and Boston Scientific Corporation shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. Boston Scientific Corporation neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

Warranty Shipments, Returns, and Adjustments

A warranty claim must be made promptly and must be received by Boston Scientific Corporation during the applicable warranty period. Should it become necessary to return a product for repair and/or adjustment, a Return Authorization (RA) must be obtained from the Boston Scientific Equipment Service Business (1-800-949-6708). Boston Scientific Corporation will provide instructions as to how and where products should be shipped. Any product or component returned for examination or for warranty repair shall be sent insured and prepaid via the means of transportation specified by Boston Scientific

Corporation. Shipping charges for all products or components replaced or repaired under warranty shall be the sole responsibility of the buyer. In all cases, Boston Scientific Corporation has sole responsibility for determining the cause and nature of a product's or component's failure, and Boston Scientific Corporation's determination with regard thereto will be final.

Decontamination of Returned Equipment

To comply with United States postal and transportation laws, equipment returned to Boston Scientific Corporation must be properly decontaminated with a chemical germicide that is approved for use as a hospital disinfectant. If equipment is received without having been decontaminated, Boston Scientific Corporation will charge cleaning costs to the customer.

Limitations

- This warranty does not cover the Imaging Catheter, Catheter Simulators, or OEM equipment that is not included in the System Console.

- This warranty does not cover normal calibration, cleaning, or maintenance of the system.

- Any product returned to Boston Scientific Corporation without prior authorization shall be returned at sender's expense.

- Boston Scientific Corporation reserves the right to change or discontinue this product's specifications without prior notice.

Conventions and Symbol Definitions

The following conventions are used throughout this manual:

Warning or Caution labels on the outside of the **Galaxy™ System**, or those listed in the User's Guide and Service Manual, represent potential hazards for the operator, service personnel, and the patient.

WARNING

A **WARNING** indicates that **PERSONAL INJURY OR DEATH** may occur to patient and/or user if the user does not observe the provided information.

CAUTION

A **CAUTION** indicates that **DAMAGE TO EQUIPMENT** may occur if the user does not observe the provided information.

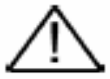
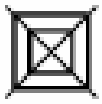
PRECAUTION

A **PRECAUTION** indicates that **INCONVENIENCE TO THE USER** (such as loss of text entries or saved settings) may result if the user does not observe the provided information.

IMPORTANT

IMPRORTANT or **NOTE:** Indicates there is **ADVISORY** information that is important for you to be aware of.

Symbol Definitions

	This symbol is used to draw attention to information that may relate to safety of the patient, the operator, or the equipment.
	This symbol indicates that the equipment is not Category AP, and therefore must not be used in the presence of flammable liquids or gasses.
	This symbol indicates that the equipment on which it appears is intended for defibrillator-proof direct cardiac application (type CF), and includes circuitry to limit the patient leakage current to the levels specified in UL 2601-1, EN 60601-1, and JIS-T-0601-1.
	This symbol indicates that the equipment does not utilize a floating double insulated isolation connection, and therefore must not be connected to external equipment that is not protectively earthed (DO NOT connect to class II equipment).
	Non-ionizing radiation may be produced by this device.
V	Voltage
Hz	Hertz, cycles per second
AC	Alternating current
VAC	Voltage of an alternating current
A	Amperes (current)

mm	millimeters
ms	milliseconds
IPX4	Splash proof. When the sterile cover (Drape) is attached to the Motordrive and an Imaging Catheter is inserted into the Motordrive/sterile cover system, that combined unit is splash proof (IPX4) per IEC 529.
	This symbol indicates that the System may be affected by Electro-Static Discharge (ESD) on or near the System's rear panel connectors when power is applied. Avoid touching the rear panel connectors or making connections when the System has power applied.

Usage Precautions and Warnings

Warnings

Inappropriate use of the **Galaxy™ System** may lead to patient injury or death. Please read the **Galaxy™** or **Galaxy™2** User's Guide and the package inserts for the imaging catheters carefully and completely before attempting to use the System.

To achieve proper grounding reliability, the power plug must be fully inserted into a receptacle marked 'Hospital Grade." If there is any question of power outlet or power cord integrity, do not proceed. Obtain qualified technical assistance.

To reduce the risk of electric shock, DO NOT connect the **Galaxy™ System's** input or output connections to equipment that is not protectively earthed -- grounded (DO NOT connect to class II equipment).

For continued protection against fire hazard, replace fuses only with listed and certified fuse of the specified type and rating indicated on this label located on the Console rear panel:

NOTE: The box bisected with a line indicates a fuse, "**T A**" indicates the fuse type, and "**VAC**" indicates the alternating current voltage rating. The values appropriate for your System will be entered (e.g., T8A, 250 VAC, etc.)

The Power-on/Standby Switch on the rear panel does not immediately remove AC power from the System internally. There may be lethal potentials within the **Galaxy™ System** even when the power cord is disconnected due to the Un-interruptable Power Supply operation. The only power indication is the System Display Screen.

Possible explosion hazard if used in the presence of flammable anesthetics.

The **Galaxy™ System** employs a floating double insulated patient isolation connection within the **Galaxy™ System** Motordrive Unit. This connection is intended for defibrillator-proof direct cardiac application (type CF), and includes circuitry to limit the patient leakage current to the levels specified in UL 2601-1, IEC 60601-1, and JIS-T-1001.

Use only Imaging Catheters that are specifically approved for the **Galaxy™ System**. Refer to the Directions for Use supplied with the specific Imaging Catheter to determine certification for use with the **Galaxy™ System**. If the proper identification of a connected Imaging Catheter is not displayed on screen, do not proceed with its use.

Prior to initiating and during automatic pullback, ensure that the Motordrive/Sled combination is in a stable position and will not fall. Failure to do so may jeopardize patient safety.

For instructions on proper disposal methods for the following consumable items, please refer to the Directions for Use packaged with the item:

- Sled
- Motordrive Drape
- Imaging Catheter

These items may be contaminated and must be handled accordingly.

The Imaging Catheters used with the System are designed for single patient use only. Do not reuse or re-sterilize catheters. Previously used or re-sterilized catheters may result in patient injury or death. Refer to the *Catheter Directions for Use*, packaged with each catheter.

Instructions in the User's Guide for Imaging Catheter preparation are provided for general guidance only. Always follow the Directions for Use packaged with each Imaging Catheter.

Cautions

If the System will be stored in a location where power cannot be applied (to maintain the battery in a charged state) for over thirty days, contact Boston Scientific Service; as the battery should be removed from the System to help prevent potentially hazardous conditions as a result of the battery deteriorating.

If the hemostasis valve seal is tightened excessively, the rotating imaging core within the Catheter may become pinched, which can damage it, or cause image artifacts. (This is not a patient risk issue).

To prevent the **Galaxy™ System** from interfering with other sensitive electronic equipment, and for full compliance with "IEC60601-1-2 Collateral Standard: Electromagnetic Interference", the System should only be used in an X-ray shielded room.

Be aware of the potential hazards associated with the environment into which the equipment will be installed. Boston Scientific cannot anticipate these for you.

Incorrect connections to the Overhead Monitor Switchbox may cause loss of video to external monitors. The external video capabilities require an initial setup procedure prior to use. Boston Scientific's Field Service personnel must work in conjunction with your biomedical engineers to implement this capability. Contact Boston Scientific for details, including a list of compatible video formats.

The Overhead Monitor Switchbox is used to connect the **Galaxy™ System** IVUS System to the overhead monitor. When connecting cables, match symbols on cabling with symbols on the Overhead Monitor Switchbox.

Never remove the MO Disk Cartridge without using the Eject Button, or data loss, or damage to the Drive and/or Disk may occur.

Galaxy™ System power must be in Snooze or Standby mode when connecting or disconnecting external equipment, including the Motordrive and the Lemo® Cable to the Overhead Monitor Switchbox. Never connect or disconnect the Motordrive's cable when the **Galaxy™ System** is operational.

The **Galaxy™ System** and/or the external equipment can be damaged if signal levels are not appropriate. If equipment not specifically authorized by Boston Scientific is to be connected, it must meet all applicable electrical safety standards that apply to the **Galaxy™ System** in order to maintain the **Galaxy™ System** *'s* safety integrity. Any equipment not supplied by Boston Scientific must be initially connected by Boston Scientific.

Ensure that the Imaging Catheter is carefully inserted through the opening in the Imaging Catheter Drape, without catching any part of the Bag between the Imaging Catheter and the Motordrive.

Never attempt to connect, or disconnect an Imaging Catheter to the Motordrive while it is running, or damage to the Imaging Catheter or Motordrive may occur.

If the Imaging Catheter currently connected to the Motordrive is not the same type as the Procedure Catheter displayed, measurement results may be invalid. Always connect an Imaging Catheter of the same type as displayed as "Procedure Catheter" while making measurements.

Do not change types of Imaging Catheters during a Run or invalid measurement results may result.

If an Imaging Catheter that has not been approved for use with the **Galaxy™ System** is connected, or if a Catheter is not properly connected, the corresponding Imaging Catheter identification data and Displayed Depth will not be displayed. Imaging will be disabled. Resolve this issue before continuing use. The System and/or the Imaging Catheter could be damaged if a Catheter is connected that is not approved for such use.

For best results, do not attempt to manually move the Motordrive once it is installed in a Sled without the use of the Release Lever, or damage to the Sled may occur.

Do not allow anything to obstruct the pathway of the Motordrive on the Sled, as this will interfere with proper pullback motion.

Never attempt to re-use the disposable Sled for subsequent procedures. Its internal movement mechanism was not designed for prolonged usage. Repeated usage will result in wear that will degrade measurement accuracy.

A number of the components devices used with the **Galaxy™ System** (*e.g.*, the imaging catheter, disposable sled, motor drive cape) are for single patient use only. Reuse, reprocessing, or re-sterilization of these devices may compromise the structural integrity of such devices and lead to device failure which, in turn, may result in inaccurate measurements, patient injury, illness, or death. Carefully review the directions for use of each component used with the **Galaxy™ System** for reuse precautions.

Boston Scientific Corporation assumes no liability with respect to single use devices that are reused, reprocessed, or re-sterilized, and makes no warranties, expressed or implied (including the warranties of merchantability or fitness for a particular use), with respect to such devices.

Do not apply adhesive labels (other than circular labels designed specifically for CD-R labeling) on the CD-R. Other labels may unbalance the CD-R; or come loose, potentially damaging the Drive or CD-R.

Improper setting of the DDP or Reject selections may obscure diagnostically valuable information in the display.

The default Gray Scale Map has been pre-selected as being appropriate for most imaging circumstances. Improper setting of this selection may obscure diagnostically valuable information in the display.

The **Galaxy™ System** is immune to in-band RF interference at field strengths less than 32 mV/m. When imaging in the presence of in-band signals that are greater than 32 mV/m, the interference may appear on the monitor as bright speckles, snow, spokes, white background, or other forms. In extreme cases, the interfering signal may render the image unreadable until the transgressing signal is terminated.

Per IEC60601-1-2 Collateral Standard: Electromagnetic Interference for patient connected systems, the immunity levels for external electromagnetic interference is 10mV/m for the **Galaxy™ System**.

Medical Ultrasound Safety

Anyone using the **Galaxy™ System** for human procedures of any kind should thoroughly understand the implications of such use. The AIUM (American Institute of Ultrasound in Medicine) has published a document titled *Medical Ultrasound Safety* (AIUM 1994). ALARA is an acronym for the principle of prudent use of diagnostic ultrasound by obtaining the diagnostic information at a power output that is As Low As Reasonably Achievable. To obtain a copy of this document, please contact the AIUM.

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Regulatory Information

United States Federal Law restricts this device to sale by or on the order of a physician, licensed by the law of the jurisdiction in which they practice, to use or order the use of this device.

Ultrasound scanning of human subjects for medical diagnostics should only be performed by qualified medical professionals. Although there have been no confirmed adverse effects produced by diagnostic levels of ultrasound, unnecessary exposure should be avoided.

The **Galaxy™ System** meets the acoustic output emission guidelines established by the Food and Drug Administration (FDA) and the International Electrotechnical Commission (IEC). The total ultrasonic power emitted from the imaging catheter has been measured, using a calibrated hydrophone and an automated drive system to scan the acoustic field around the catheter tip when it is immersed in water. In order to maximize the measured values, the intensity of the ultrasound beam was determined with the calibrated hydrophone as near to the surface of the catheter as possible (the **Galaxy™ System** drives the imaging catheters in B-mode only).

Guidelines for measurements and definitions of terms may be found in:

1) *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* issued by the FDA, U.S. Department of Health and Human Services, Center for Devices and Radiological Health, Sept. 30, 1997.
2) IEC publication 60601-2-37, which establishes particular requirements for the safety of ultrasonic diagnostic equipment and those aspects thereof which are directly related to safety.

Safety Standards

Relevant Safety Standards

All Boston Scientific instruments, cables and diagnostic ultrasound imaging catheters have been designed to meet all appropriate requirements contained within UL 2601-1 (Standard for Medical Electrical Equipment Part 1: General Requirements for Safety), IEC 60601- (Medical Electrical Equipment Part 1: General Requirements for Safety), and JIS-T-1001 (General Requirements of Medical Electrical Equipment), including limits for current leakage and isolation from primary power line. Chapter 22 of Volume 2 of the **Galaxy** User's Guide provides information pertaining to FCC and IEC compliance.

Instrument Enclosure

The **Galaxy™ System** is a Class I protectively earthed (grounded) System. The main AC inlet Isolation Transformer is certified to be in compliance with EN 60601-1, and limits the enclosure leakage currents to non-patient connected levels in both normal and single fault conditions. The System Enclosure leakage current is tested during production on all Systems for various primary power and ground conductor faults.

System Inputs and Outputs

The System's isolation panel and hi-line video connectors provide a 500V dielectric withstand between the System's I/O connectors and the System's enclosure to prevent

unwanted voltages and/or currents from flowing to the System's enclosure. Both isolation barriers operate on safety extra low voltage (SELV) circuits only.

Patient Isolation

The **Galaxy™ System** employs a floating double insulated patient isolation connection within the **Galaxy™ System** Motordrive Unit. This connection is intended for defibrillator-proof direct cardiac application (type CF), and includes circuitry to limit the patient leakage current to the levels specified in UL 2601-1, EN 60601-1, and JIS-T-0601-1.

CE 0197

The CE marking in the labeling of **Galaxy™²** signifies compliance with the European Medical Device Directive 93/42/EEC.

The CE marking in the labeling of **Galaxy™** signifies that at the time of manufacture **Galaxy™** complied with the European Medical Device Directive 93/42/EEC. **Galaxy™** is no longer manufactured, refurbished, or otherwise available for sale from Boston Scientific.

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Chapter 2 Specifications

This chapter provides electrical, connection, physical and environmental specifications.

Galaxy™

Type	Parameter	Value
Electrical	Power requirements	120 VAC, 60 Hz (U.S.) 220 VAC, 50/60 Hz 100 VAC, 50/60 Hz (Japan) 230 VAC, 50/60 Hz (Europe)
	Power consumption	Nominal 5 A @ 120 VAC Nominal 6 A @ 100 VAC Nominal 2.7 A @ 220/230 VAC Maximum 650VA
	Catheter frequency	9-40 MHz
	Safety	Class I per IEC 60601-1, UL2601-1, JIS-T-1001 Applied part (Motordrive) Defibrillation-proof type CF
Input/Output Connectors	RF Output	Analog RF Waveform
	RF-I Output	Future use
	RF-Q Output	Future use
	RF Trigger Output	Future use
	ECG Input Signal	± 1.0 V max. swing (factory default setting)
	P1, P2 Pressure Inputs	Future use
	LAN In/Out	Future use
	RS-232 In/Out	Future use
	Video In/Out	RS-170 525-60 PAL 625/50 Siemens 1023/60, 1249/50, 1023/120 GE 1023/60, 1249/50 Philips 1049/60, 1166/76 Shimadzu 1125/60
	Video Output	Impedance = 75 Ohm NTSC (RS-170(A)) Compatible, 525 lines, 60 Hz, (U.S. and Japan)

Type	Parameter	Value
		Isolated S-video (Y - C), Output Impedance = 75 Ohm
Physical	System weight Shipping weight	445 lbs. / 202 Kg. 705 lbs. / 320 Kg.
	System dimensions	64” H, 30” D, 24” W 163 cm H, 76 cm D, 61 cm W
	Crate dimensions	73” H, 47” D, 39” W 185 cm H, 119 cm D, 97 cm W
Environmental (operating)	Temperature	+10 to +40 °C
	Relative humidity	30 to 70 %
	Pressure (P)	700 to 1060 hPa
Environmental (Storage/transit)	Temperature	-10 to +50 °C
	Relative humidity	10 to 85 %
	Pressure (P)	500 to 1060 hPa

Ordering Information

Galaxy™2
IVUS Imaging System

GALAXY™2 SYSTEM TECHNICAL SPECIFICATIONS

Processor:	Pentium® 4 2.4 GHz
Operating System:	Windows NT®
Database Structure:	Microsoft Access®
Digital Archiving:	Hard Drive 120 GB DVD+RW over 3.5 GB CDR 650 MG
Dimensions:	64″H (LCD open) or 48″ H (LCD closed), 30″D, 24″W
System Weight:	377 Lbs.
Shipping Weight:	695 Lbs.
Frequency of Operation:	9–40 MHz
Catheter Compatibility:	All Boston Scientific Ultrasound Imaging Catheters
Power Requirements:	100–240 VAC, 50/60 Hz
Monitor:	17″ LCD Flat Panel Monitor (Foldable)
Monochrome Digital Graphic Printer:	Gray Scale, 256 Shades
VCR:	NTSC
Input/Output:	RS232, ECG Input, Pressure 1&2 Input, RF Trigger Output, RF Output, Composite Video Output, S-VHS Video Output, LAN
Safety Standards:	Class 1 per EN 60601-1, UL2601-1, JIS-T-0601-1
Environmental:	(Operating) Temperature +10 to +40˚C
MD5-Motordrive Unit:	Handheld Imaging Controller
OMS-Overhead Monitor Switchbox:	(Not Included–Order) X-ray Integration

ORDERING INFORMATION

H749I51280 (120 V, NTSC):	Galaxy™2
Hardware Accessories	
H749A70200:	Galaxy Disposable Pullback Sterile Sled
H749A70260:	Galaxy Motordrive (MD5) Sterile Cover
H749019330010:	Sony Printer Paper UPP-110HD

Boston Scientific

Chapter 3 Introduction to the Galaxy™ System

This chapter explains the capabilities and uses of the **Galaxy™ System**. It includes important information on the **Galaxy™ System's** unique features.

This chapter is introductory in nature and intended to provide service technicians with a broad overview of the **Galaxy™ System**. Please refer to the **Galaxy™** or **Galaxy™²** User's Guide for more specific details regarding system operation.

Overview

The **Galaxy™ System** Intravascular Ultrasound System (IVUS) provides state-of-the-art real-time viewing of internal vascular structures such as coronary and peripheral arteries, and intra-cardiac applications.

The **Galaxy™ System** sets new standards in diagnostic capabilities and efficiency-of-use in the Imaging Lab through its wide range of advanced features, such as:

- Integrated Automatic Pullback Subsystem offering quick preparation and lightweight design.
- Longitudinal vessel view, to aid in interpretation and analysis.
- Enhanced display modes, including split screen views of IVUS, Longitudinal view and angiographic views.
- IVUS image display on overhead monitors.
- Real-time digital procedure storage capability with 'bookmark' capability.
- Computer-aided linear and area measurements, including computation of Cross-sectional Area (CSA) and Percent Stenosis.
- Luminal and vessel border detection using TraceAssist™.
- Image quality enhancements in gray scale, display quality, and blood speckle reduction.
- Read/write DVD, CD-ROM and/or Magneto-optical (MO) disk drives for digital archiving of procedures and reports.
- Real-time audio recording captures comments during procedures.
- Semi-automatic Report Generation.
- A Patient Database.
- Automated archiving to DICOM Network

- Familiar ‘windows-like’ user interface.
- A task-optimized ergonomic Control Panel.
- An integrated back-up power supply supports quick relocation.

Key Features and Functionality

The **Galaxy™ System** offers a wide range of important features to aid in intra-vascular imaging.

High Resolution Display

A high resolution SXVGA (1280 x 1024) 17-inch color CRT-type monitor or LCD display is provided, with an integrated microphone to record procedure-related conversations.

Figure 2 On-screen controls – Graphic User Interface (GUI)

For ease of use, the on-screen controls utilize the familiar Windows point-and-click interface. The auto-hide menu bar further simplifies the interface.

NOTE: Some images are shown in reversed grayscale for improved clarity when printed.

Multiple Image Display

The **Galaxy™ System** can simultaneously display up to three modes at once, including:

IVUS Display

The IVUS image can be displayed full screen, or as a quarter screen when combined with other display modes. The **Galaxy™ System** automatically switches the IVUS display to quarter screen when the LongView™ imaging mode is selected.

Longitudinal View (LongView™)

The **Galaxy™ System** provides a fully integrated longitudinal view (LongView™) display, where a sequence of tissue data frames are acquired during a System-controlled transducer pullback, and displayed congruent to the blood flow. An adjustable "cut-plane" indicator selects a two-dimensional slice through the imaged vessel, perpendicular to the conventional cross-sectional IVUS image for the LongView™ display. The **Galaxy™ System** can also use ECG gating for selection of IVUS frames used for the LongView™ display. ECG gating helps minimize tissue border artifacts caused by the cardiac cycle.

X-Ray Display

The **Galaxy™ System** can display an externally-sourced X-ray image full screen, or as a quarter screen. Like the IVUS display, the X-ray Display is switched to the quarter screen when the LongView™ display mode is selected.

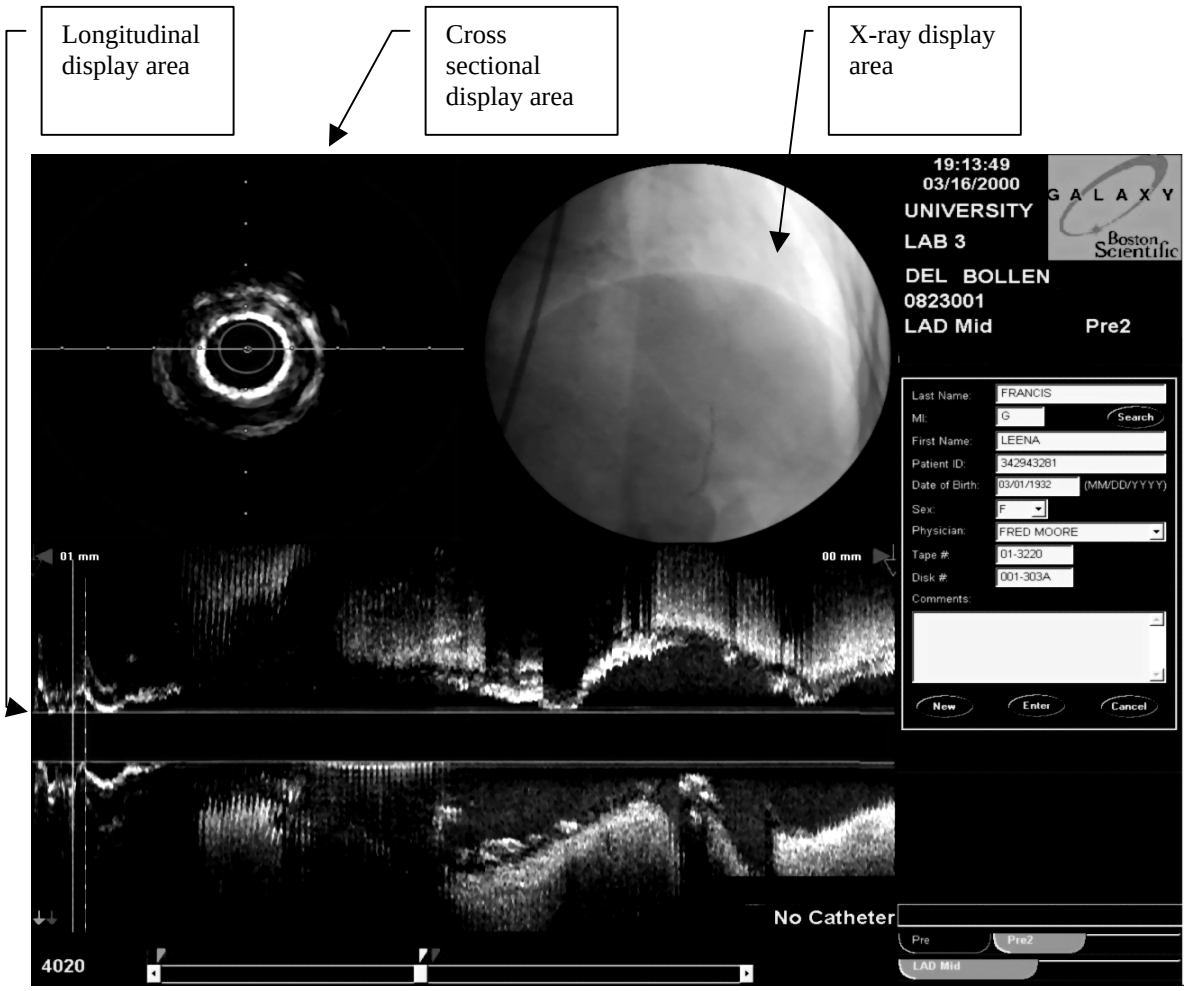


Figure 3 Cross sectional, LongView™, X-Ray image displayed

Pre-Post Display

The **Galaxy™ System** can also display simultaneous side-by-side viewing (not shown here) of two procedures for comparison. The System divides the normal image viewing area into two windows, and automatically displays the DiskView Window, which is used to select the Bookmarked images to be displayed in these two windows.

Overhead Display Compatibility

The IVUS screen can be displayed on most imaging overhead monitors to aid in visualization of the IVUS imaging by others in the lab. An Overhead Monitor Switchbox (OMS) is placed in the lab, and provides connections between the **Galaxy™ System** and the existing overhead imaging X-ray display. The module also identifies the specific lab to the **Galaxy™ System.** This allows the System to automatically configure to the lab's

video requirements (after initial setup has been done) when it is relocated. Your biomedical engineers must work together with Boston Scientific personnel to implement this capability. Please contact Boston Scientific for details, including a list of compatible X-ray video formats.

Refer to Chapter 7 for more information regarding the Overhead Monitor Switchbox option.

Control Panel

Functions used during a normal IVUS procedure are provided via a task-efficient Control Panel, optimized according to the flow of an IVUS procedure. Settings used less frequently are provided via on-screen menus, to streamline operations. Controls are back-lit to aid visualization in reduced light environments, and indicate when a control is activated.

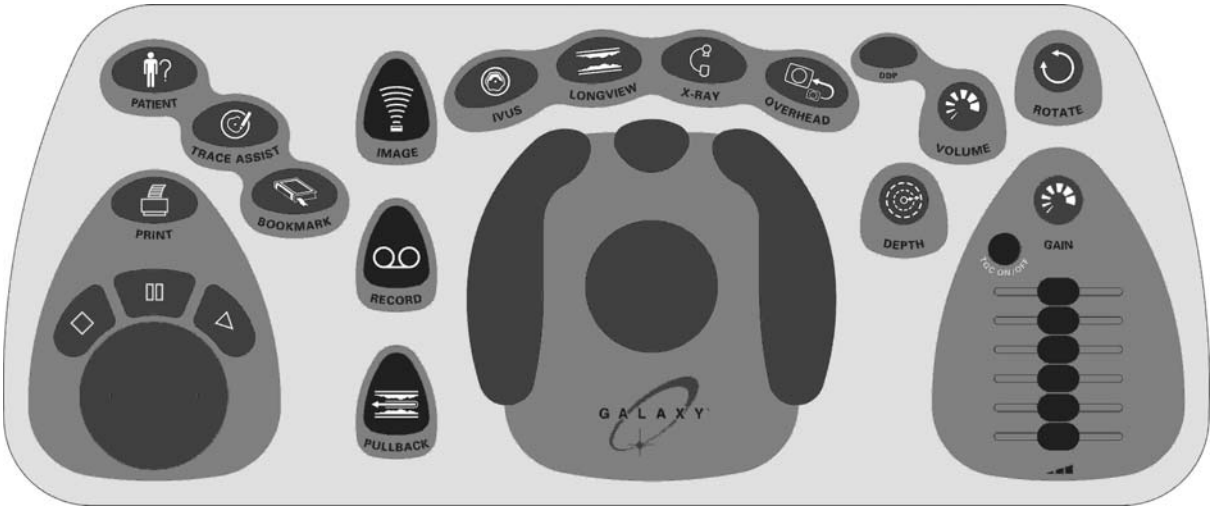


Figure 4 Control Panel

Digital Image Storage and Retrieval

The **Galaxy™ System** stores IVUS images in digital format to preserve image quality, optimize review time, and enable computer-aided image enhancement and measurement/analysis capabilities. Digital storage includes the internal Imaging Hard Disk, magneto-optical (MO) disk, CD-R, or DVD+RW in either the **Galaxy™ System** or DICOM format. DICOM (Digital Imaging and Communications in Medicine). Network storage of **Galaxy™ System** studies is also supported. The System can retrieve and play back locally stored IVUS images in real-time as a continuous loop, as if they were "live".

Bookmarking

The Bookmarking feature is used to identify regions of interest during or after image acquisition, providing easy review of key image data by clicking the Bookmark. Bookmarks can be set either while recording or playing images. If an X-ray image is displayed on the **Galaxy™ System** at the time the Bookmark is created, it will be stored along with the IVUS record.

Other data that is stored with a Bookmark, in addition to the displayed IVUS and X-ray images (as available), are:

- Frame (index) number
- Displayed measurement and annotation information
- The current display format (LongView™, etc.)
- Depth setting
- Imaging Catheter

Bookmarks can be used during review to quickly retrieve a single IVUS frame (or single LongView™ sequence). Additional Bookmarks can be set during image review.

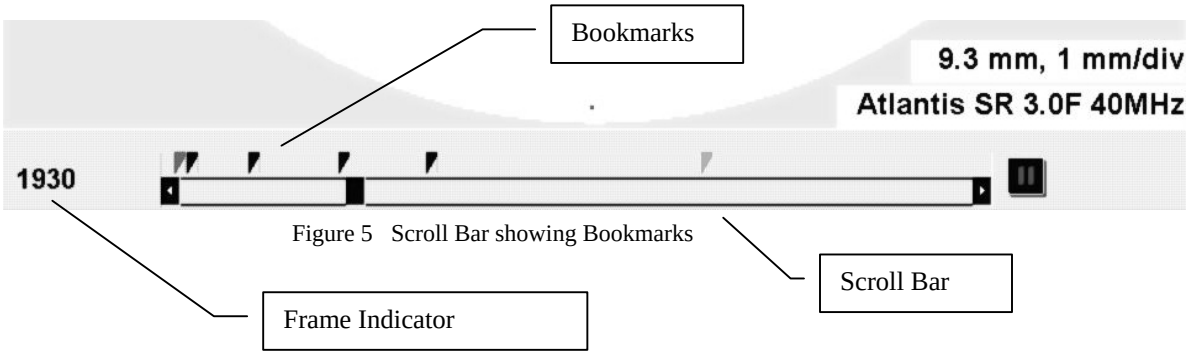


Figure 5 Scroll Bar showing Bookmarks

Measurement Capabilities

The **Galaxy™ System** provides accurate and efficient measurements. The measurement feature allows up to six linear cross-sectional measurements. As each linear measurement is completed, that distance appears on screen. When an area is defined, the **Galaxy™ System** can automatically determine the minimum and maximum diameter within that area, and the Cross-sectional Area (CSA). The **Galaxy™ System** facilitates measurements in the LongView™ display, which may help determine lesion length.

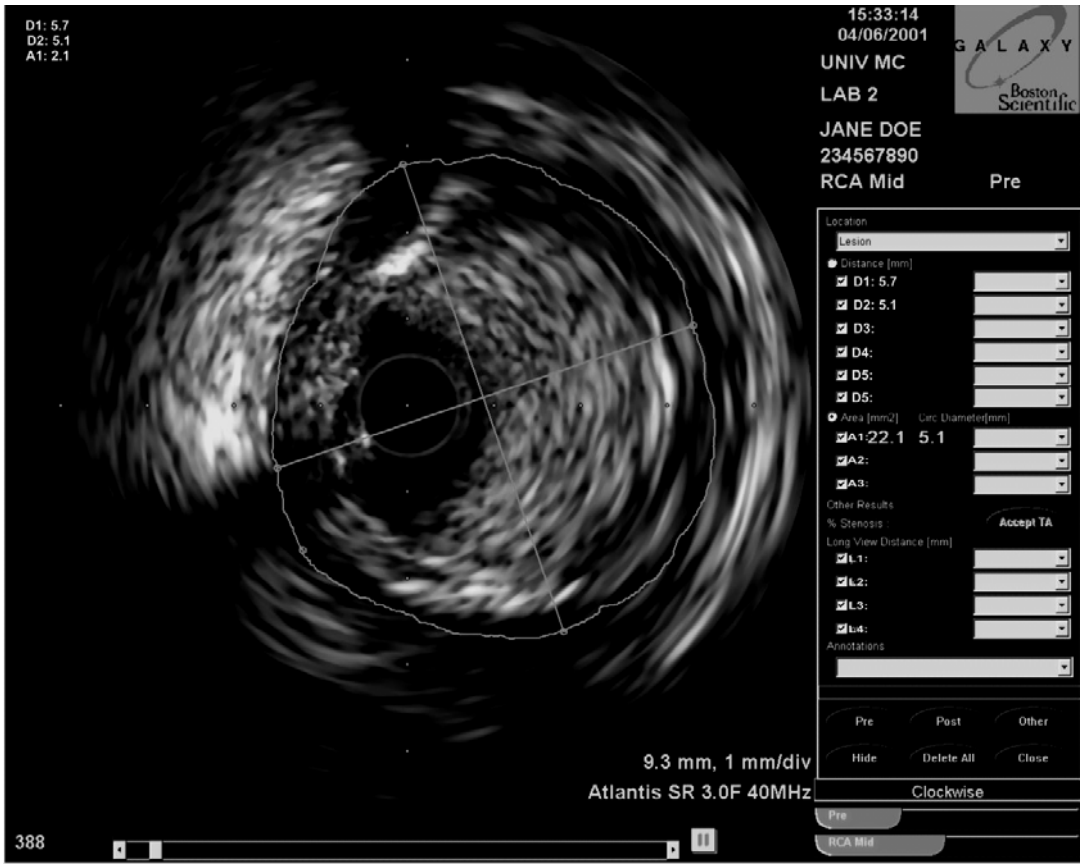


Figure 6 Measurement Example

TraceAssist™

The **Galaxy™ System** also offers a TraceAssist™ feature that uses computer image analysis to automatically detect and identify the cross-sectional luminal and vessel border. The computer-generated border is easily modified, if desired.

Motordrive and Pullback Sled

The Motordrive provides the rotation of the Imaging Catheter Core required for cross-sectional imaging of a vessel. With the aid of the Sled, the Automatic Pullback function provides a constant rate of longitudinal movement of the Imaging Catheter Core. This allows the **Galaxy™ System** to provide longitudinal (LongView™) displays of the pullback area. The disposable Sled is used for a single IVUS procedure, which can consist of multiple pullbacks. The System displays pullback distance information on the Motordrive's integrated display, and on screen.

The Motordrive is placed in a sterile disposable drape (cover) during use. The disposable Sled is sterile, eliminating the need for a second sterile cover for the Sled, which simplifies setup.

Other Automatic Pullback features include:

- Selectable pullback rate: 0.5mm/sec or 1.0 mm/sec
- Pullback distance displayed on the Motordrive, on-screen, and (optionally) overhead
- Optional synchronization to an external ECG input
- No external power (battery) requirements

The Motordrive and Automatic Pullback Subsystem are compatible with applicable Boston Scientific Imaging Catheters.

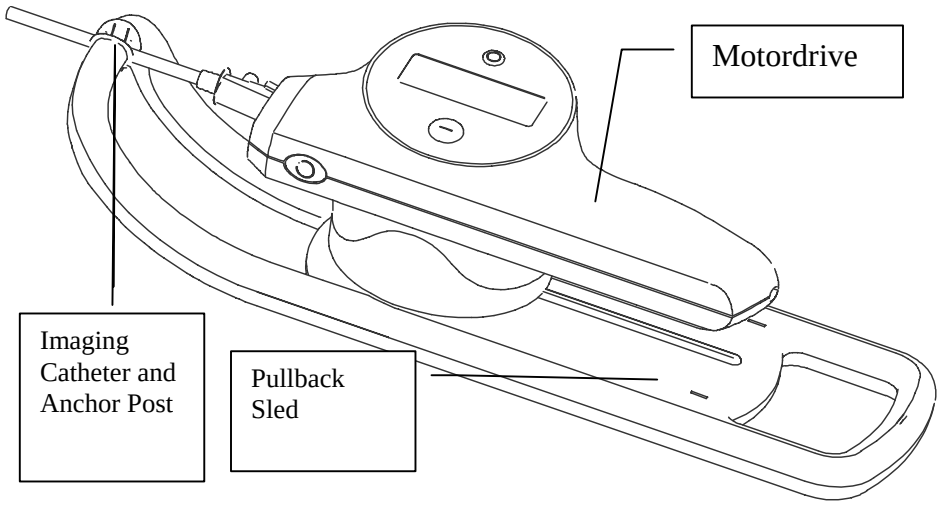


Figure 7 Pullback Sled with Catheter & MDU

Printer

A high-resolution graphics printer is incorporated into the **Galaxy™ System** Console. The Printer is operated by pressing the Print Button on the **Galaxy™ System** Control Panel, and provides high-resolution monochrome prints of the display. Print results are also saved as a file on the System Imaging Hard Disk. These can be located in the File Manager and are listed as "screenshots." These screenshots are bitmap (*.BMP) files that can then be copied to CD-R or DVD+RW and removed from the system for viewing on any PC.

VCR

The **Galaxy™ System** includes an SVHS-format VCR integrated into the Console. The VCR is operated using its built-in front panel controls. It can also be configured to record automatically when the Record Button is pressed on the **Galaxy™ System** Control Panel. VCR and digital image playback are independent of each other.

Image Storage

The **Galaxy™ System** offers two selections for how images are stored during acquisition; 1) to the Imaging Hard Disk only 2) to the Imaging Hard Disk and the VCR. By default, images are initially digitally stored on **Galaxy™ System's** internal Imaging Hard Disk to provide the digital cine-loop capability. The acquired images can also be simultaneously recorded by the VCR for (analog) storage on videocassette.

DICOM 3 Storage Support

The **Galaxy™ System** provides conversion of IVUS procedures performed on the System into DICOM (Digital Imaging and Communications in Medicine) formatted multiple frame series of images, or single frame images. The **Galaxy™ System**'s DICOM-formatted images are intended for viewing off the System at Viewing Stations capable of displaying images in the DICOM 3 *Ultrasound* modality, or *IVUS* modality.

The System can store the images it converts to DICOM format on its internal disk drives (System Hard Disk, MO, CD-R, DVD+RW). Additionally, if the System has been configured into a DICOM network, it can also store DICOM-formatted images to Storage Servers on that network, on either an immediate basis, or from a queue on a scheduled basis.

Using the System to Acquire Images

The following sections describe how the **Galaxy™ System** features explained in the previous sections are utilized to perform an IVUS procedure.

Note: This information is introductory in nature. Typical clinical implementation is not described herein.

Initializing the Galaxy™ System

Normally the System is maintained in a power-on state, ready to begin imaging immediately. The **Galaxy™ System** has an internal power supply that will allow the System to enter a standby (Snooze) mode (without imaging) for several minutes, allowing it to be unplugged and relocated without shutdown and start-up delays. This feature also provides protection against loss of imaging data in the event that the System is accidentally unplugged during a procedure.

If the System is powered off, a switch located on the Console initiates the power-up sequence, and within a few moments it is ready for use without any further operator intervention.

Patient Data Entry

The Patient Button (or menu selection) provides access to the Patient Window, and the Patient Search function, which queries the Database for previous entries for a patient. The System is also configured to allow initialization of a procedure without first entering the patient data when an emergent situation arises, although pre-entry is recommended.

Patient data (and procedure-related) data entries include:

- Last Name
- MI (Middle Initial)
- First Name
- Patient ID
- Date-of-Birth
- Sex
- Physician
- Tape Number
- Disk Number
- Comments

Only the patient's last name and ID (identification number) are required entries.

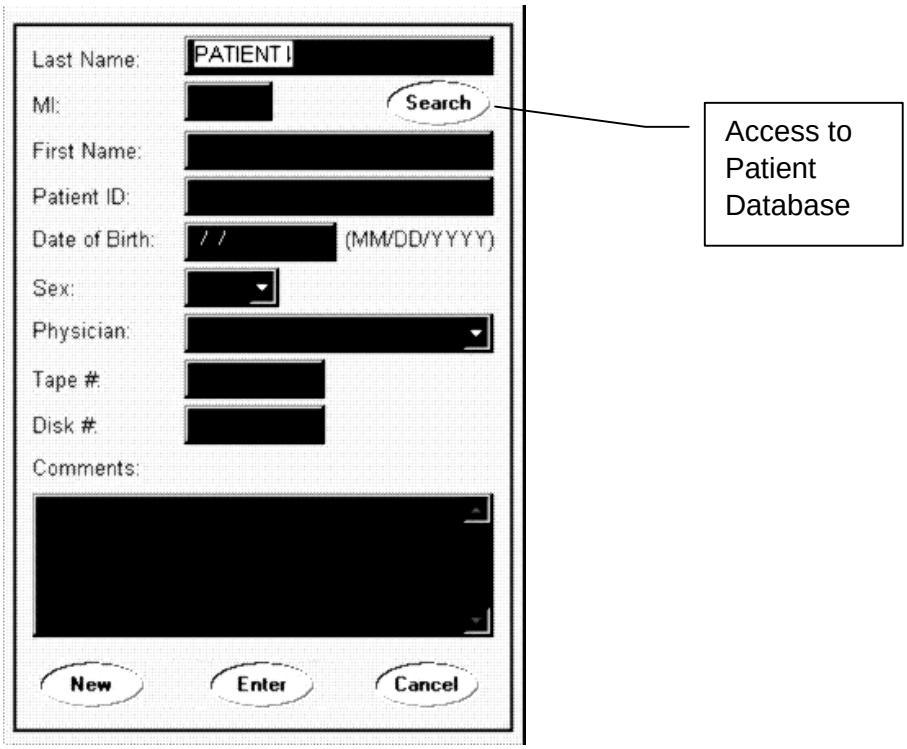


Figure 8 Patient Data Entry Window

Vessel and Run Data

The **Galaxy™ System** facilitates identification of the vessel being imaged and of each scan of the vessel (called a "Run"). Entry of this data facilitates computer-assisted measurements, report generation, and image archival features. Each Run can last up to five minutes (or longer, when using an ICE Imaging Catheter), and contain up to ten centimeters of longitudinal information.

Some examples of Run identifications are:

- **Pre** – used to identify imaging done before a procedure.
- **Post** – used to identify imaging done after a procedure.
- **Stent** – used to identify imaging of stent deployment.

Commonly used procedures and devices are provided in the selection list, with the capability to add others

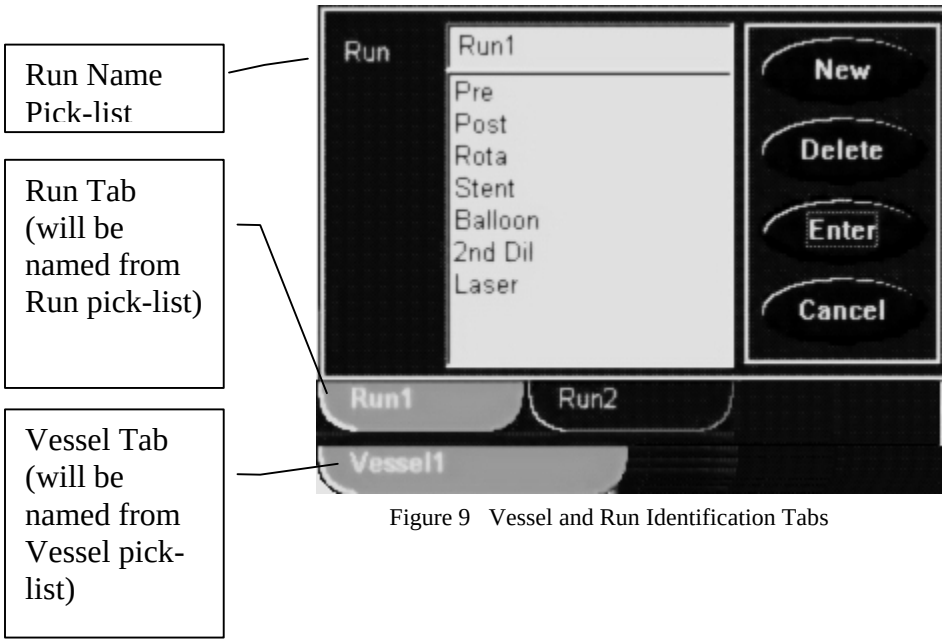


Figure 9 Vessel and Run Identification Tabs

Imaging

Imaging is started or stopped using either of two Image Buttons. One is located on the Control Panel of the Console and the other is located on the Motordrive.

Optimizing the Image

Several controls and settings are available for optimization of the displayed image (although this is not normally necessary). These are:

TGC Sliders

Time Gain Control (TGC), allows segmented changes in gain relative to the distance from the Transducer.

Note: TGC settings are automatically set according to the (automatically detected) characteristics of the Imaging Catheter currently connected. A button adjacent to the (normally off) TGC controls can be pressed to activate these controls.

Gain Knob

The Gain setting controls the overall echo intensity.

Depth Knob

The Depth control provides a "zoom" (magnification), which can be used to obtain a more detailed view of the region nearest the Transducer. Depth is not adjustable during an automated controlled pullback using the disposable sled.

Rotate Knob

The Rotate control allows rotation (re-orientation) of the cross-sectional IVUS image for convenient viewing.

DDP Knob

Data Dependent Processing (DDP) provides sophisticated image processing that can help remove "blood speckle" in the image resulting from reflections from (moving) blood cells.

Reject Setting

The Reject setting allows elimination of low-level signals that may result in noise clutter in the image.

Gray Scale Map

Gray Scale Mapping allows selection of how echo intensities are translated into the black-through-white image intensity display.

Note: The default values of all of these settings have been optimized for most imaging situations. Improper alteration of these settings may degrade image quality or obscure diagnostically significant information.

Pullback

The Automatic Pullback Subsystem consists of the Motordrive and the Sled. Use of the Automatic Pullback Subsystem is required when the System's LongView™ imaging mode is utilized. If longitudinal movement is to be done while imaging, the Automatic Pullback Subsystem offers a more uniform result than can normally be attained through manual movement. There are two available pullback rates – 0.5 and 1.0 mm/second (0.5 is the recommended setting). The pullback motion can be started and stopped from the Pullback Start/Stop Buttons located either on the Motordrive, or on the Control Panel. Image acquisition can also be synchronized to an externally supplied ECG input, to reduce the effects of heart motion on the images.

Pullback Sled

The **Galaxy™ System** uses a disposable pre-sterilized Sled to provide uniform longitudinal movement. The Pullback Sled enhances the operation by reducing draping and sterilization requirements. The Motordrive unit (required for all imaging) is draped and then inserted into the corresponding receptacle (cup) in the Sled. The Imaging Catheter is then connected to the Motordrive, and its Anchor Housing is inserted into the Anchor Post at the nose of the Sled.

The Motordrive can be manually moved along the Sled when the Release Lever (at the rear of the Motordrive) is pressed. The Motordrive also has a digital position readout, and a button to zero the reading at the desired point. The pullback distance is displayed both on the Motordrive's display and on the **Galaxy™ System** screen.

Audio

The **Galaxy™ System** is equipped with a Microphone, which is built into the Display housing. User comments are recorded whenever images are being recorded. (The playback can be turned off if desired).

Saving Settings

The **Galaxy™ System** offers a wide range of settings to allow optimization of its operation. The default values established by Boston Scientific for these settings are optimized for most imaging situations based on inputs from experienced IVUS personnel. Those default values are stored as the "**Galaxy™ System** Default" Preset.

After using the System, if you have changed any of the following parameters, those changes (along with other un-altered settings) can be saved as a separate Preset. Storable parameters include:

- Recording device(s) (e.g., VCR, MO Disk, etc.)
- Time and date format
- TGC settings
- TraceAssist™ settings
- Grid settings
- Reject level
- Gray Scale
- DDP setting
- Pullback speed
- Audio settings
- X-ray source
- Current Imaging Catheter type

- Display Mode
- Parameter Display mode
- Depth Setting
- Grid off/on state

Multiple Presets with differing content can be saved, and can be named with intuitive keywords (such as a procedure type or user's name)

The **Galaxy™ System** default preset values are permanently stored in the System, and can be applied at any time, allowing quick restoration of those settings. The default preset values cannot be altered.

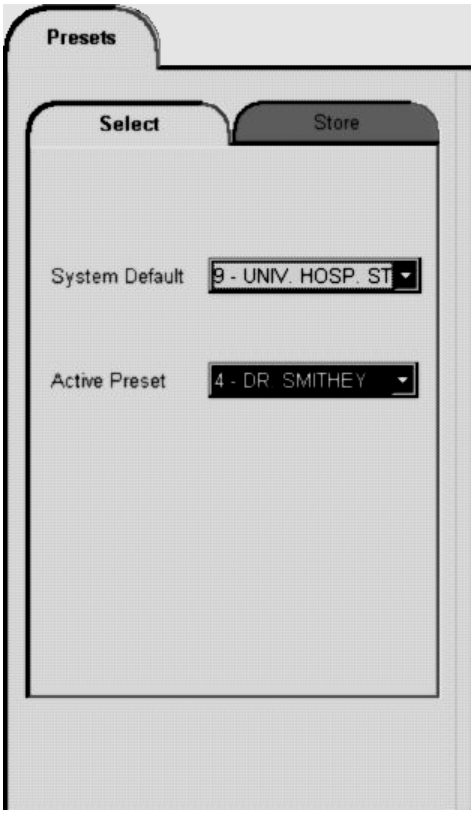


Figure 10 Preset Selection Window

Using the System to Review Images

The following sections describe how the **Galaxy™ System** features explained in the previous sections are utilized in reviewing IVUS images. Image Review is the "normal" mode, and is automatically implemented when no other mode is selected.

Image Review Source

Most image review operations are performed immediately following acquisition. That image data is normally stored on the Imaging Hard Disk. Other possible review sources are the MO Drive, CD-R & DVD+RW Drive, and VCR. The Patient Database feature can be used to quickly locate previous procedures.

Reviewing Digitally-stored Images

The Disk Review controls on the Control Panel mimic VCR control functions, allowing Play, Jog, Shuttle, Pause, and Stop features. The current Run will play in a continuous loop if desired. The Shuttle control can function as a variable speed fast-forward or reverse, with rates from 12 to 120 frames per second (normal frame rate is 30 FPS).

Additionally, the controls provided on the Scroll Bar below the image, and the Frame Counter display can be used to move through the selected Run.

During review, any previously saved image overlay features (e.g., Grid, Measurements, Annotations) will be displayed, and the original Depth setting will be maintained. If a Run is being reviewed in the LongView™ mode, the Cut Plane Indicator in the cross-sectional area of the display can be re-located to any position (using the Trackball), and the LongView™ display will be updated accordingly. The Trackball can also be used to reposition the Current Frame Cursor in the LongView™ display, and the cross-sectional area of the display will be updated accordingly.

Reviewing Videocassette Images

If the archive is on tape, once the appropriate videocassette is inserted, the VCR's front panel controls can be used to review the procedure. Most measurement functions are also available for use in VCR review.

Measurements

The **Galaxy™ System** supports area-based (Cross Sectional Area, CSA) and distance-based analysis measurements on still cross-sectional IVUS images; and distance measurements on still cross-sectional and LongView™ images. Up to six distance measurements and four area measurements are supported on cross-sectional images; and four additional vertical (size) and horizontal (length) measurements in the LongView™ section. Distance and area measurements are intended for lumens, vessels, and stents.

Computer Assistance

Computer-aided features make measurement operations more efficient. When two area measurements are made, one within the other, the **Galaxy™ System** will automatically identify the larger measurement as the vessel, and the smaller measurement as the lumen. When three area measurements are made within each other, the **Galaxy™ System** will automatically identify the larger measurement as the vessel, the mid-sized measurement as the stent, and the smaller measurement as the lumen. When area measurements are performed, the maximum and minimum cross-sectional distances are also calculated and displayed.

TraceAssist™

Additional computer assistance is available to automatically identify the peripheral borders of the vessel and the lumen. This feature is called "TraceAssist™". If enabled, the System detects the borders of the vessel and lumen and displays a graphical overlay where they are detected. You can either accept the computer selection, or edit it (move the border tracing).

Measurement results are displayed both in the image area and in the Measurement Window. If a measurement is to be included in a System-generated Report, it must be identified using a convenient pick-list.

Annotate

Text Annotations can be added to the image display. The Annotation function is accessed from within the Measurement and Annotation Window. A pick-list of pre-set annotations is available for selection. Free-form text can also be entered.

Procedure Reports

The **Galaxy™ System** provides a Patient Database and a powerful Report Generator, which helps to streamline documentation of the IVUS procedure. Many entries in the

Report are automatically transferred from patient and vessel information entered earlier in the procedure, as well as measurement results. Other key information is easily specified by selecting commonly used terms from pick-lists. Only a minimal amount of information remains to be typed in (if desired).

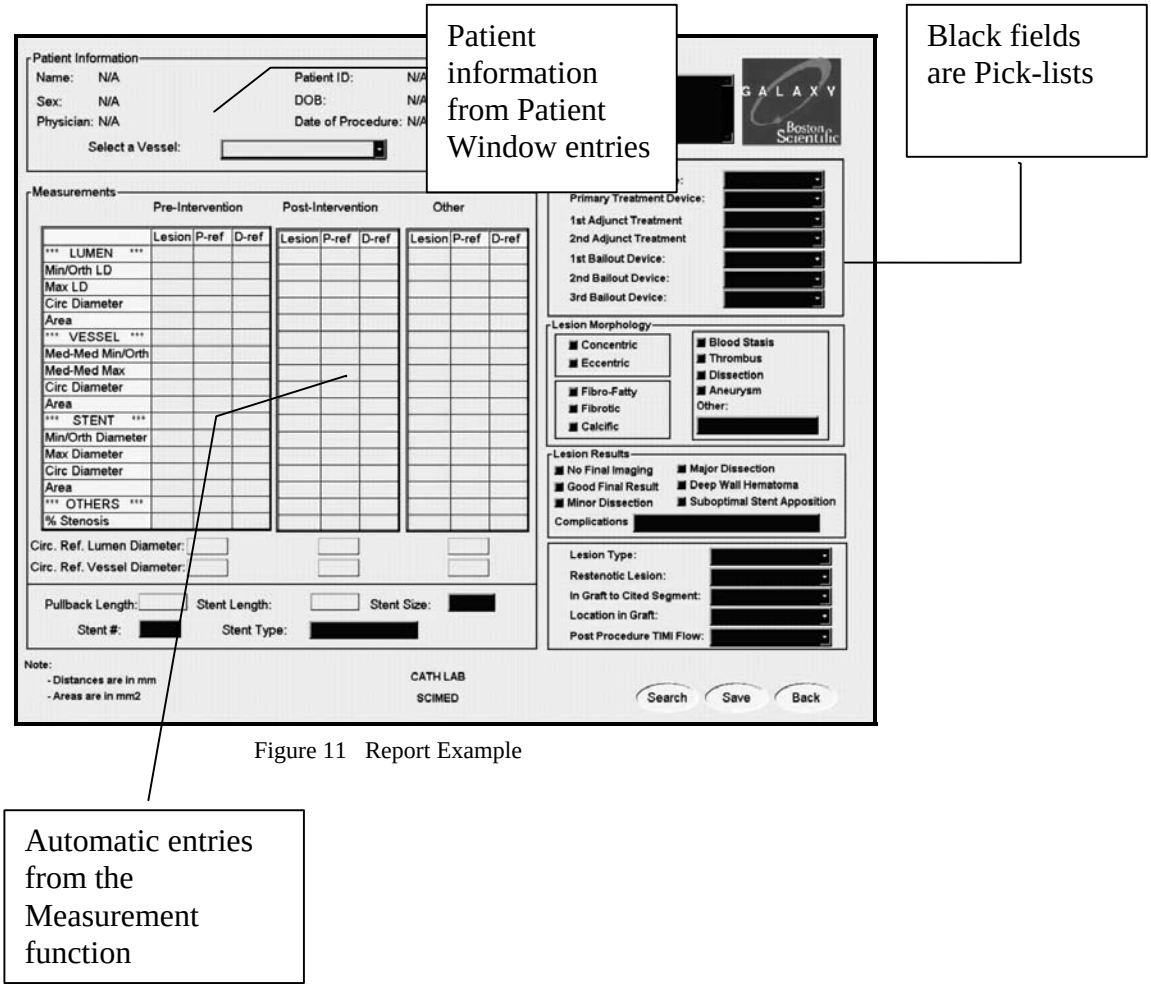


Figure 11 Report Example

Entries

Once the patient and vessel have been selected, the Report Generator fills in the entries in the Measurement section that correspond to those measurements made during the study of that vessel.

Items Reported

Selectors are provided to expedite completion of the Report in the following areas:

- Procedure Device(s)
- Lesion Morphology
- Lesion Results
- Lesion Type

In addition to the pre-set selections, free-form text entry fields are also provided.

When the Report is complete, simply click the Save Button. To obtain a hard copy of the Report, press the Print Button on the Control Panel while the Report is displayed.

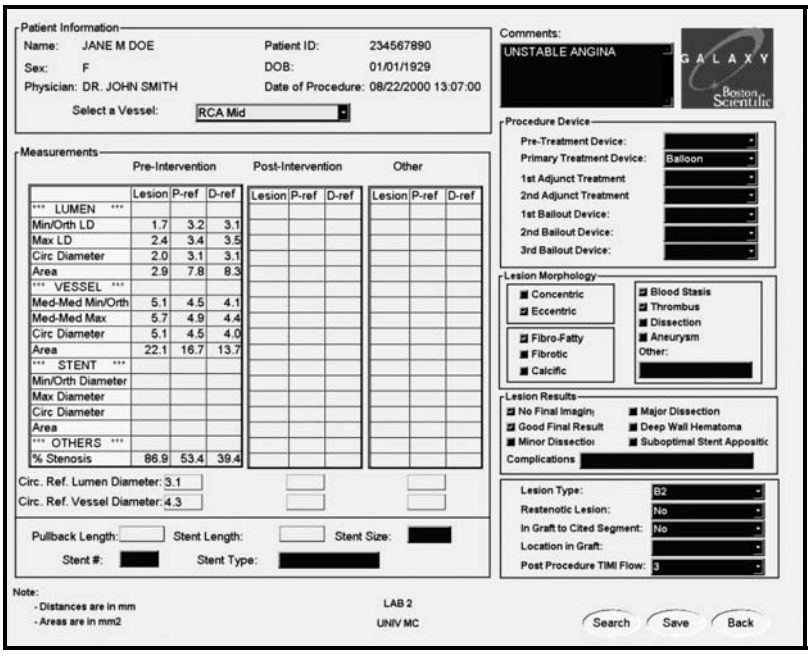


Figure 12 Completed Report Example

Archiving Images

Manual Archiving

Patient's images can be manually copied between any of the following digital storage devices:

- Imaging Hard Disk
- MO disk
- CD-R or DVD+RW disk

This is accomplished using the DiskView Window in the Files Menu.

DICOM

The **Galaxy™ System** can store the images it converts to DICOM 3 *IVUS* or *Ultrasound* format on its internal disk drives (System Hard Disk, MO, CD-R, DVD+RW). Additionally, if the System has been configured into a DICOM network, it can also store

DICOM-formatted images to Storage Servers on that network, on an immediate basis or from a queue on a scheduled basis.

Other

The VCR can also be used as an automatic archive (while performing the procedure), although digital archiving is recommended.

IVUS Procedure Archiving

The **Galaxy™ System** provides internal storage for images and patient records, but these must be archived to either a removable digital media such as DVD, CD-ROM or MO disk, so that those images can be manually deleted from the Imaging Hard Disk to free up storage space for future procedures. Saving patient studies on videocassette is also a viable cost-effective alternative, although image quality will not be as good as digital media options.

Entering File Mode

The Technologist accesses the File Menu, then selects the patient and their procedures, and then indicates which storage device will be utilized to archive the data.

Chapter 4 Functional Description

Purpose

This Chapter provides basic functional descriptions of **Galaxy™** and **Galaxy™2** components and their interrelationship so that operating principles may be understood.

Scope

This Chapter is not intended to provide a detailed theory of operation. The following information is intended to provide Service Engineers and Technicians a broad and basic understanding of **Galaxy™ System** components and their interrelationship.
Such information may aid the servicing of **Galaxy™ Systems**.

Overview

The **Galaxy™ System** is Boston Scientific Corporation's Intravascular Ultrasound system (IVUS). The system provides the same ultrasound imaging capabilities as Boston Scientific's earlier model, ClearView® Ultra™, with improvements to its display and archival capabilities. The new display capabilities include, a color graphical user interface (GUI), the ability to import x-ray hi-line and export IVUS hi-line video, and a real time Longitudinal view. The new archival capabilities includes a digital cine loop, and the ability to save to CD-R, DVD+RW, or Magneto Optical (MO) disks, depending on the **Galaxy™ System** version. These new capabilities are achieved with proprietary hardware & software and an Embedded Windows NT computer assembly.

Detailed Description

Motor Drive 5 (MD5) assembly

The major functions of the MD5 are:

- Transmit and receive the ultrasound pulses
- Identify the catheter type in use
- Rotate and locate the angle of the motor shaft (i.e., catheter)
- Pullback and locate the imaging core relative to the catheter sheath

The MD5 is a defibrillator proof type CF applied part. It contains the transmitter, receiver, catheter drive motor, catheter optical encoder, catheter identification and patient isolation circuits. In addition, it contains an embedded micro-controller, a numeric LCD

display, a sled optical encoder, and a sled motor to control and report the uniform linear movement of the MD5 when mated to a sled. This linear movement enables the acquisition of uniformly spaced image frames that are used to create the longitudinal view.

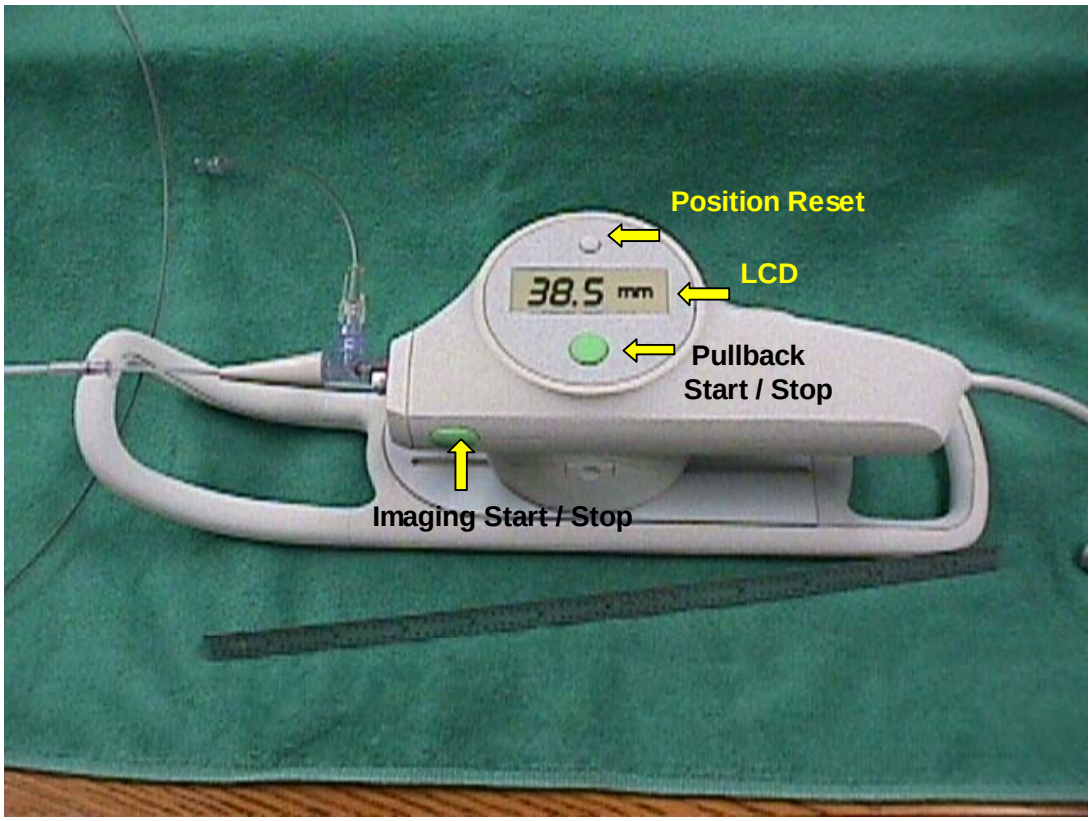


Figure 13 MD5 Motor-Drive Unit

Image acquisition assembly

This assembly is a VME-based embedded computer, with a 68000-based 6U VME board, a fourth generation acquisition and control board (ACQ4), a fourth generation Radio Frequency (RF4) processing board, a third generation high voltage (HV3) board, and an interconnect board.

68000 computer

This 68000 computer executes a proprietary kernel that communicates with the Windows NT assembly via an RS232 serial link. It controls and monitors all image acquisition functions within the VME image acquisition assembly. It also executes a software watchdog timer that must be pacified by the Windows NT (PC) assembly or the imaging functions are disabled.

ACQ4

The ACQ4 board controls the catheter rotational motor and receives the catheter optical encoder pulses from the MD5. The ACQ4 synchronizes all imaging acquisition functions to the catheter encoder pulses. Imaging is initiated by starting the catheter motor rotation. This causes encoder pulses to be generated which are used by the ACQ4 to create the transmit signal to the transmitter board in the MD5. The ACQ4 board also generates a Time Gain Control (TGC) signal. The TGC signal is sent to the RF4 board where it controls the gain of the received ultrasound signal as a function of elapsed time relative to the transmit signal. The ACQ4 board also digitizes the processed received ultrasound signals and transmits R/Theta image data via a high-speed serial data stream to the Windows NT computer using four LVDS (Low Voltage Differential Signal) twisted pairs.

RF4

The RF4 board processes the received ultrasound signals from the MD5 receiver board. The RF4 board varies the gain of the received ultrasound signal as a function of the TGC control signal from the ACQ4 board. It then 'band pass filters' the received signal. Finally, the signal is log compressed and detected prior to being transmitted to the ACQ4 board for digitization.

HV3

The HV3 board provides a low current selectable voltage to the transmitter output amplifier. This voltage is used to set the transmitted ultrasound power level. The High Voltage PCA (HV3-6U) generates a DC voltage in the range of 0 to 150 VDC which is fed to the transmitter PCA in the Motor-drive unit (MDU).

Interconnect

The interconnect board provides noise filtering and connectivity between the acquisition assembly and the other assemblies within the **Galaxy™ System**.

Windows NT computer assembly installed in Galaxy™

The Windows NT computer assembly contains a 300W power supply, a DEC passive back plane, a Single Board Computer (SBC), a Matrox graphics/frame grabber video board, a PCI Buffer (PBUF) board, a PCI Scan Converter (PSC) board, a Merlin Video Conversion Function (VCF) board, a National Instruments AD board, a Comtrol serial I/O board, a 16 bit sound board, a 10/100BaseT Ethernet board, two Adaptec SCSI boards, a Magneto Optical (MO) drive, an 18GB cine-loop Hard Disk Drive (HDD), and a 9GB System HDD.

DEC passive back plane

The DEC passive back plane provides 12 PCI slots, in 3 groups of 4, interconnected by 2 PCI to PCI bridge chips, and 3 ISA slots connected via an ISA bridge chip.

SBC

The SBC has two Pentium II 400MHz processors, 512Mbytes of SDRAM, an IDE controller, two Ultra Wide SCSI controllers, a PS2 mouse port, a PS2 keyboard port, and two RS232 serial ports. The operating system for the SBC is Windows NT embedded. The SBC provides basic Windows NT services to **Galaxy™** . The SBC also executes a 5 frame Finite Impulse Response (FIR) filter within software that is identical to the 5 frame FIR filter used in ClearView®.

PBUF

The PBUF PCA resides between the PC PCI bus and the VME PESS ACQ4 R-Theta output port. The PBUF buffers incoming R-Theta data from the ACQ4 PCA and makes this data available to the PCI bus. The PBUF is a PCI based dual port frame buffer board with a high-speed digital input port. The PBUF buffers each frame (256 8 bit samples per vector times 256 vectors per frame) of sample values before transferring the data onto the PCI bus.

National Instruments A/D board

The National S/D card is an ISA based data acquisition board having multiple digital I/O and three analog inputs. The digital I/O is used to communicate the status of the system power to the Windows NT computer assembly. The analog inputs are used to input an analog ECG and two physiological inputs for digitization. All digitized outputs are provided to the computer assembly via the ISA bus.

Comtrol serial I/O board

The serial I/O board provides 4 RS-232 serial I/O ports for communication. One RS-232 port is connected to the System Isolation Panel for external access. Another is used to communicate and control the status of the embedded micro-controller within the MD5 that controls the linear movement of the MD5 on the sled. Another serial port is used to control and communicate the status of the VCR within the system.

16 bit sound board

The sound card has an audio line input and output, a microphone input, and a speaker output. The sound card is used to record and play back digital audio from the system cine loop and analog audio from the VCR. The microphone is used to input audio into the **Galaxy™** for digital and analog recording. The speaker is used to playback both analog and digital audio. The line output is used to provide analog audio to the VCR for recording. The line input is used to playback analog audio from the VCR. The ISA bus transfers all digital audio to and from the system.

10/100BaseT Ethernet board

The board is a PCI based Ethernet card having a digital I/O port that supports both 10BaseT and 100BaseT communication networks. The digital I/O port is connected to the System Isolation Panel for external access.

Adaptec SCSI controllers

The Adaptec SCSI controllers are PCI based SCSI cards with high speed parallel digital interfaces compliant with the SCSI3 specification. The SCSI card on the R-Theta PCI bus is used to forward the R-Theta and digital audio data to the Cine-loop HDD. The SCSI card on the Primary PCI bus is used to archive digital data to the CD-R or the MO drive and to provide digital data to the SCSI page printer for printing.

MO Drive

The MO Drive has a SCSI2 bi-directional data port. The MO Drive provides the ability to record digital case data onto and play back digital case data from MO media. The MO Drive provides the ability to archive up to 30 minutes of IVUS digital data.

18GB HDD

The 18GB Hard Disk Drive provides up to 90 minutes digital cine-loop storage.

9GB HDD

The 9GB Hard Disk Drive maintains the operating system, **Galaxy™** application, and the patient database.

Windows NT computer assembly installed in Galaxy™²

The **Galaxy™²** PC Subsystem hardware contains the following components:

An active motherboard including the with the following:

- ATX V2.03 form factor
- A Pentium 4 2.4 GHz 400 MHz Front-side bus
- 1024 Mbytes of DDR266 SDRAM
- Two (2) IDE interface ports supporting the Ultra ATA/100 hard drive interface standard capable of over 10 Mbytes/sec of sustained data transfer
- 100 Mbps Ethernet LAN connectivity
- Audio function capable of multimedia recording and playback
- Two (2) RS-232 serial ports
- One (1) parallel port
- One (1) PS/2 keyboard port
- One (1) PS/2 mouse port
- Audio output port for “Audio Line Out”
- Audio input ports for “Audio In” and "Microphone In"
- Six (6) 33 MHz 32-bit 5 volt PCI slots

PCI slots are populated with the following:

- PBuf PCA as described herein
- PSC PCA as described herein
- Matrox Graphics/Frame Grabber PCA as described herein
- Optionally, VCF PCA as described herein

- Four (4) Port Multi-serial PCA capable of sustaining serial transfer of 9600 Baud Rate each
- General-purpose I/O PCA with at least four (4) digital input TTL-level channels, four (4) digital output TTL-level channels, and three (3) 12-bit A/D channels

ATX P4 12VDC Power Supply with a minimum output of 400 Watts.

Mass Storage Devices:
- Two (2) internal-mount ATA-100 120 Gbyte 7200 RPM hard drives with minimum sustained data transfer of 10 Mbytes/sec for each drive
- One (1) internal-mount IDE bus 4.7 Gbyte DVD+RW drive. The drive is capable of writing to CD-R and DVD+RW media and reading from CD-ROM, CD-R, DVD-ROM, DVD+RW media
- One (1) internal-mount 3.5" floppy drive

Windows NT computer PCA's common to both Galaxy™ and Galaxy™^{2}

1) PSC

The PSC is a PCI based scan converter board with a digital parallel input port and an output port. The scan converter converts the 8 bit R-Theta (Polar) sample value into 8 bit X-Y (Cartesian) pixel values. The data is converted based on a weighted four point interpolator having 4 bit per point resolution (i.e. each X-Y pixel value is calculated based on a 4 –bit relative weighting of the 4 nearest R-Theta sample values.)

2) Matrox graphics/frame grab

The Matrox graphics/frame grabber video board is a PCI based video board with two digital parallel input ports, an analog frame grab input port, and an SXVGA output port. The main video display simultaneously combines the following main overlays:

- Real Time Tissue Ball Input Digital Video
- Real Time X-ray Input Digital Video
- Post Processed or Archived Digital Video (from PCI Bus)
- Menu Graphics

The Tissue Ball data is able to be input from both the PCI bus and a dedicated digital video bus.

The menu graphics input is from the PCI Bus.

The video board has two independent display memories. This allows for non-destructive graphic overlay onto real time images. One of the digital parallel input ports is used to input the scan converted real time IVUS data and the other is used for the real time x-ray data.

The Graphics/Frame Grab system provides input capture of video from a SVHS VCR The analog frame grab port is used to input the VCR video output. This input captures SVHS (Y/C) and transfers this to the Graphics/Frame Grab display memory.

3) Merlin VCF

The VCF is a PCI based video conversion board having an SXVGA input and two passthrough output ports, a Main System Digital Video output port, an x-ray digital video input and parallel output ports, and a VCF to VIF Input/Output (I/O) control port. The VCF provides two SXVGA buffered outputs and converts the x-ray digital video from the Merlin Video Isolation Function (VIF) board into the **Galaxy™ System** SXVGA video format and the analog **Galaxy™ System** SXVGA video into a digital black and white x-ray video format. The SXVGA passthrough output ports provide the **Galaxy™ System** video to the **Galaxy™ System** monitor for display and to the SXVGA to SVHS video converter for recorded onto SVHS videotape. The Main System Digital Video output port provides digital black and white **Galaxy™ System** video in the x-ray video format to the Merlin VIF board for display on the overhead x-ray monitor. The x-ray digital video input port provides digital black and white x-ray video to the VCF for conversion to the **Galaxy™ System** video format. The digital video parallel output port provides x-ray video in the **Galaxy™ System** video format to the Matrox video board for display on the **Galaxy™ System**. The VCF to VIF control I/O port provides communication and control data between the Merlin VCF and VIF boards.

Control Panel

The Control Panel has an RS232 bi-directional data part, a Trackball output port (Microsoft 3 button mouse compatible), and user accessible buttons, knobs, and slide pots. The control panel is used to control the basic imaging functions of the **Galaxy™ System**. Please refer to the **Galaxy™** or **Galaxy™²** User's Guide for specific details on Control panel operation.

Figure 14 Control Panel Functions

Keyboard

The keyboard has a standard PS2 keyboard input port. The PC compatible keyboard is a splash resistant US English style PC keyboard. The keyboard does not contain any special or non-standard keys.

Monitor or LCD Display

The **Galaxy™** monitor or **Galaxy™2** LCD display has a standard SXVGA input port. The display is a color computer display at 1280 x 1024 resolution with a 72 Hz refresh rate.

Printer

The printer will generate a black and white (B&W) print of the current image on the monitor.

- The **Galaxy™** printer (Mitsubishi Digital CP-700DSU) has a SCSI2 bi-directional data port. The printer is a SCSI color photo-realistic page printer, although only B&W is enabled. The printer is configured (in Windows NT) to cut following each print.

- The **Galaxy™²** printer is a standard PC-type B&W page printer (SONY Digital UP-D895) connected to the parallel port (LPT1) of the computer.

VCR

The VCR utilizes the S-Video input, S-Video output, Video output, audio input and output ports, and a bi-directional RS232 control port. The S-Video input is NTSC or PAL compatible. The S-Video output port is the NTSC or PAL video output from the S-VHS tape to the Matrox frame grabber. The VCR Video output provides NTSC or PAL video output to the isolation panel. The Audio input receives case audio form the sound card for recording to videotape. The Audio output provides audio from tape to the sound card for playback from tape. The RS232 port provides command, control, and status information to and from the VCR. The VCR is an S-VHS (Super VHS capable) VCR for recording case audio and video onto tape.

CD-R Drive

The **Galaxy™** CD-R Drive has a SCSI2 bi-directional data port. This drive is external to the PC enclosure. The CD-R Drive provides the ability to record digital case data onto and play back digital case data from CD-R media.

DVD+RW Drive

The **Galaxy™²** DVD drive has an IDE bi-directional port. This drive is internal to the PC enclosure. The DVD drive provides the ability to record digital case data onto and playback digital case data from CD-R, CD-RW, DVD+RW type media.

PC UPS Assembly

The PC UPS assembly contains a UPS Power Supply, a PCA Power Distribution board, and a PCA PDS Control board. The PC UPS Assembly provides batteries based power to the Windows NT computer assembly and the monitor in order to facilitate graceful operating system shutdown in the event of power loss, and to allow for system transportation between catheter laboratories without necessitating an operating system shut down and reboot. All imaging modalities of the **Galaxy™ System** are disabled when the **Galaxy™ System** is drawing power from its internal batteries.

UPS Power Supply

The UPS power supply receives isolated AC main power and provides AC mains battery backed-up power to the PCA Power Distribution.

PCA Power Distribution

The PCA Power Distribution board receives isolated AC main power and battery backed up power and distributes AC power to the **Galaxy™ System**.

PCA UPS Controller

The PCA UPS Control board has multiple digital connections between the National Instruments A/D card and the PCA power Distribution board. The PCA UPS Controller board reports the status of AC power to the Windows NT computer assembly. The PCA UPS Controller board also monitors the health of the operating system via a watch dog timer. The PCA Power Distribution board commands the distribution of AC power throughout the **Galaxy™ System** by controlling the PCA Power Distribution board.

Peripheral Equipment

The **Galaxy™ System's** peripheral equipment includes a Merlin VIF, an Extron SXVGA to SVHS converter, a CD-R drive (**Galaxy™** only), and a system Isolation Panel. The **Galaxy™ System's** peripheral equipment is defined as assemblies located outside the Motor Drive 5, Image acquisition, Windows NT computer assemblies, excluding the User interface assemblies, and within the **Galaxy™ System's** enclosure providing needed functionality.

Merlin VIF

The Merlin VIF board has a Main System Digital Video input port, an x-ray digital video output port, an analog **Galaxy™ System** video output port, an x-ray video input port, a VCF control I/O control port, and a x-ray control output port. The VIF is the Signal Input Part/Signal Output Part (SIP/SOP) for the **Galaxy™ System** hi-line (x-ray) video. It provides a 500VAC dielectric boundary between the **Galaxy™ System**, x-ray video, and the x-ray control signals and the two SXVGA buffered outputs and converts the x-ray digital video from the Merlin Video Isolation Function (VIF) board into the **Galaxy™ System** SXVGA video format and the analog **Galaxy™ System** SXVGA video into a digital black and white x-ray video format. The SXVGA passthrough output ports provide the **Galaxy™ System** video to the **Galaxy™ System** monitor for display and to the SXVGA to SVHS video converter for recorded onto SVHS videotape. The Main System Digital Video output port provides digital black and white **Galaxy™ System** video in the x-ray video format to the Merlin VIF board for display on the overhead x-ray monitor. The x-ray digital video input port provides digital black and white x-ray video to the VCF for conversion to the **Galaxy™ System** video format. The digital video parallel output port provides x-ray video in the **Galaxy™ System** video format to the Matrox video board for display on the **Galaxy™ System**. The VCF to VIF control I/O port provides communication and control data between the Merlin VCF and VIF boards.

SXVGA to SVHS converter / Extron

The SXVGA to SVHS converter has SXVGA video input and SVHS video output ports. The SXVGA to SVHS converter converts **Galaxy™ System** SXVGA computer video from the Merlin video pass through port into NTSC or PAL SVHS video for recording onto videotape.

System Isolation Panel

The System isolation panel has the following isolated input ports: ECG, Pressure #1, and Pressure #2. The System isolation panel has the following isolated output ports: RF, RF I, RF Q, RF Trigger, **Galaxy™ System** SVHS Out, and **Galaxy™ System** Video Out. The System isolation panel has the following isolated bi-directional data ports: 10BaseT and RS232. The system isolation panel is a separation device that isolates the **Galaxy™ System** from externally connected equipment. Please refer to the users manual for specific details on provide signal inputs and outputs.

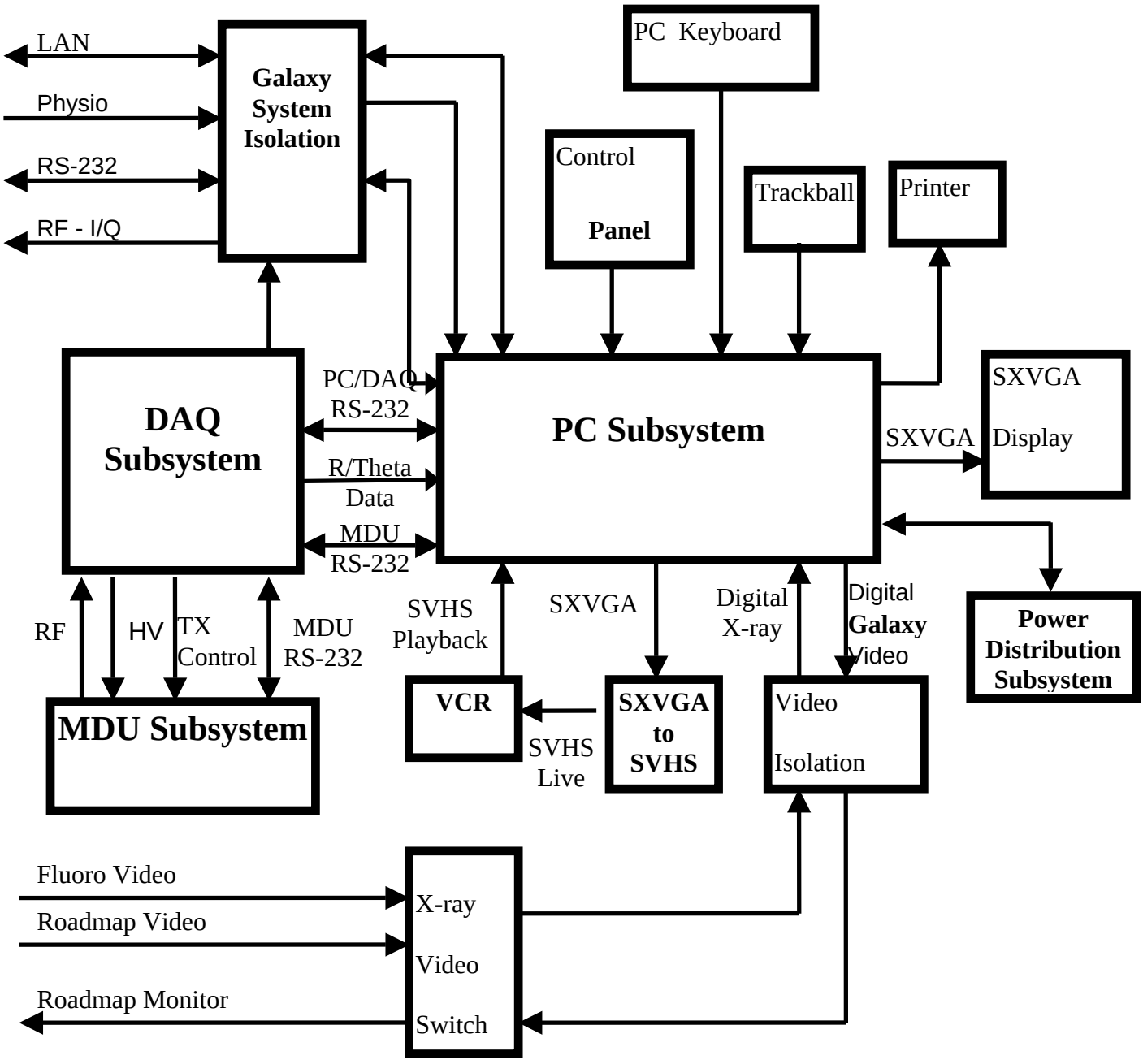
External Peripheral Equipment

The **Galaxy™ System** External Peripheral Equipment includes an x-ray Overhead Monitor Switchbox (OMS). The External Peripheral Equipment is defined as equipment that is located outside the **Galaxy™ System** console that provides **Galaxy™ System** peripheral functionality to the console. The MD5 motor drive is not considered External Peripheral Equipment because it is essential to the main function of **Galaxy™ System**.

X-ray Overhead Monitor Switchbox (OMS)

The x-ray OMS has a **Galaxy™ System** video input, a Roadmap video input, a fluoro video input, an x-ray control input, an x-ray video output, and a **Galaxy™ System**/x-ray Video Output. The **Galaxy™ System** Video Input is a black and white **Galaxy™ System** video input to the OMS that has been scan converted to the x-ray monitor line rate. The Roadmap video input is the Roadmap monitor video to the x-ray switch box. The fluoro video input is the fluoro monitor video input to the x-ray switch box. The x-ray control input provides the control signals that allow the **Galaxy™ System** to select either x-ray or fluoro video input and either fluoro or **Galaxy™ System** video output. The x-ray video output is either the Roadmap or the fluoro (depending on **Galaxy™ System** settings) video input to the **Galaxy™ System** for display on the **Galaxy™ System** monitor. The **Galaxy™ System**/x-ray video output is either the Roadmap or **Galaxy™ System** video for display on the Roadmap monitor. See Chapter 7 for more details.

Galaxy™ Hardware Block Diagrams



Galaxy™ Block Diagram

10BaseT
ECG
Pressure #1 & #2
RS-232
RF Out
RF I & RF Q (X2)
RF Trigger
Galaxy SVHS Out
Galaxy Video Out

System Isolation Panel

PC

AC main
Pwr. Dist. System (PDS)
UPS Power Supply
PCA Power Distribution
PCA PDS Control

Audio In Out
Mic
Speak
DAQ RS-232
CPAN RS-232
Control
Track
Keyboard
CD-R
Printer

ECG/Pressure #1 &
SVHS Out
VCR SVHS
VCR Video

RS-
RS-
RS-

National A/D Card
Comtrol Serial I/O Card
16 Bit Sound Card

Dual Pentium CPU
DRAM
Pentium II
Pentium II
ISA
Host PCI
SCSI Bridge
IDE
Floppy
9 Gb System HDD
SCSI2
M. O. Drive (5.2G)
PC
SCSI Bridge (Adaptec)
LAN (10BaseT)

RF, I, Q,
DAQ RS-

Data Acquisition Assy. (DAQ)
RF4
HV3
ACQ4
Force6 68000 CPU
P2 Bus
VME Bus

PRIMARY PCI BUS
DEC Passive Backplane
PCI-PCI Bridge
PCI-PCI Bridge
Spare (X,Y) PCI Slot
(R,θ) PCI BUS
(X,Y) PCI BUS

R/Thet a
Interconnect PCA
APD Contro

PCI Frame Buffer
Spare (R,θ) PCI Slot
SCSI Bridge (Adaptec)
Future (R,θ,T) Processor
Scan Convert er
Tissue Ball
Graphics/ Frame Grab
x-ray
Video Conversion Function VCF

Windows NT Computer Assy.
Cine-loop Disk Array (18Gbyte)
Future Filtered R/Theta Data
SVHS Playbac
SXVGA

Lemo® Cable
Motor Drive (MD5) Assy.

VCR SVHS Out
VCR Video
Audio In
Audio Out
VCR Control (RS-
VCR
SVHS Out
SVHS
SXVGA to SVHS converter
SXVGA
SXVGA
Console Monitor

Galaxy Video Out - RM
Roadmap
fluoro
x-ray Video Switch Box
Galaxy
x-ray
x-ray
Video Isolation Function VIF (Merlin)
Main System Digital Video - B/W 1Kx1K
x-ray (Roadmap or Flouro) Digital - B/W 30Hz
VCF

Chapter 5 Galaxy™ System Maintenance

Note: This chapter provides information on maintenance activities that can be performed by the end-user or technical maintenance personnel.

It includes information on basic care of the System, storage, cleaning, replacing fuses, considerations when relocating the System, and problem solving techniques.

Boston Scientific will also perform these tasks for you upon request, although some may not be covered by warranty or service contract. Please feel free to contact Boston Scientific for further information or support.

The following procedures assume you are familiar with the information in the *Controls, Settings, and Displays* chapter in the **Galaxy™** or **Galaxy™2** User's Guide. Please refer to that chapter for any needed clarifications.

Basic Care

Checking **Galaxy™ System** Performance

Depending on your institution's operational protocol, verification of proper **Galaxy™ System** functionality may be desirable. This can be accomplished using the Catheter Simulator. The following steps can be used to verify that the **Galaxy™ System** will generate images and give further assurance that the system is ready for use.

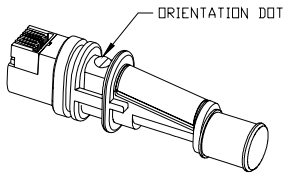


Figure 15 Simulator

1. Insert the Catheter Simulator into the end of the Motordrive, with the dot marking on the Simulator aligned with the blue-green Image Button near the end of the Motordrive. Press the Simulator firmly into the Motordrive.

Press the Image Button either on the front side of the Motordrive, or on the **Galaxy™ System** Control Panel. An image similar to that shown in Figure 16 should be displayed. You may need to adjust the Gain control on the Control Panel to achieve a similar display as Simulator results vary between Simulators

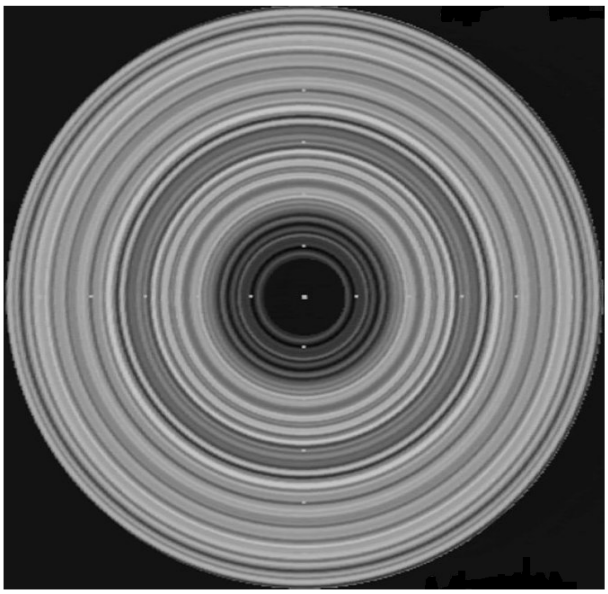


Figure 16 Typical Simulator Image

NOTE: The Catheter Simulator is not intended to detect subtle variations in system performance. When temporarily substituted for the Imaging Catheter, it can be useful in discerning whether an imaging problem is caused by the Galaxy™ System or the Imaging Catheter.

Checking the UPS Battery

The **Galaxy™ System** contains an Un-interruptable Power Supply (UPS) powered by a rechargeable battery. The charge on this battery is automatically maintained if the system remains connected to an active power receptacle. The following procedure explains how to verify proper operation of the battery:

WARNING

The Power-on/Standby Switch on the rear panel does not immediately remove internal AC power from the Galaxy™ System. There may be lethal potentials within the Galaxy™ System even when the power cord is disconnected due to the Un-interruptable Power Supply operation. The only power indication is the Galaxy™ System's display screen.

Note: This procedure should be performed every ninety days, but only at a time when the Galaxy™ System is not likely to be utilized for several hours (to allow time for the battery to recharge after this test).

1. To verify that the battery is in a ready condition, first ensure that the **Galaxy™ System** has been connected to an active power receptacle for at least five hours without the system being used.

2. Follow the instructions for "Applying Power" in the User's Guide chapter titled *Preparing the* **Galaxy™ System** *for Use*, then click the Snooze button and disconnect the power cord from the wall receptacle.

3. The **Galaxy™ System** should automatically enter the Snooze Mode with a normal display on the Monitor, and should remain in that state for at least seven minutes (if the battery is fully charged and in good condition), after which it will automatically shut down.

If you are certain that the battery was fully charged (as explained above) and the **Galaxy™ System** does not perform accordingly, contact Boston Scientific Service for assistance. There are no user remedies for UPS problems other than maintaining a full charge, as explained earlier.

Battery Maintenance

The battery in the UPS is a spill-proof maintenance-free sealed lead-acid battery. There are no user actions for battery maintenance other than maintaining it in a charged condition. This is simply done by having the **Galaxy™ System** connected to an active power receptacle as much as possible.

CAUTION

If the Galaxy™ System will be stored in a location where power cannot be applied (to maintain the battery in a charged state) for over thirty days, the UPS battery must be fully charged prior to storage. This can be accomplished by plugging Galaxy™ System in to A/C power for a minimum of 24 continuos hours.

Typical battery life is three to five years when the battery is maintained in a charged state. Leaving the battery in a discharged state reduces its life.

Replacing a Fuse

There are two fuses located at the lower rear of the Console. If the **Galaxy™ System** fails to operate, a blown fuse may be the cause. To replace a fuse:

1. Unplug the **Galaxy™ System**. It is preferable to minimize the time that the system is disconnected from power due to the internal Un-interruptable Power Supply.

WARNING

The Power-on/Standby Switch on the rear panel does not immediately remove internal AC power from the Galaxy™ System. There may be lethal potentials within the Galaxy™ System even when the power cord is disconnected due to the Un-interruptable Power Supply operation. The only power indication is the Galaxy™ System display screen.

2. To remove the Fuse Holder, pull the tab on the top of the face of the Fuse Holder outward with a small screwdriver or other tool until the Fuse Holder pops outward. The Fuse Holder can then be pulled completely out of the System.

3. Remove the fuse or fuses from the Fuse Holder and inspect. **Replace any defective fuse with a new fuse of the same type and rating as indicated on the adjacent label.**

4. Insert the Fuse Holder back into the **Galaxy™ System** in the reverse order of removal.

5. Re-connect the power cord, and test the **Galaxy™ System**. If the fuse blows again, contact your authorized service representative.

Cleaning

1. Use only a soft cloth dampened with isopropyl alcohol, Cidex®, or Cidex Plus® to wipe the Console and its accessories. Do not use harsh chemicals to clean as they may damage the finish.

2. The Trackball requires regular cleaning or poor movement response may result. Use a soft cloth dampened with isopropyl alcohol, Cidex®, or Cidex Plus® and roll the Trackball slowly while wiping it to access its entire surface.

3. Do not use disinfectants such as Gluteraldahyde or Hydrogen Peroxide to clean the Console or the accessories. Do not use acetone.

4. Do not autoclave, immerse, or attempt to sterilize the Motordrive.

Functionality Test

Purpose

Provides Field Service personnel a standardized procedure for:
1. Testing and verifying the operation and functionality of the **Galaxy™ System**.
2. Performing basic preventative maintenance.

Equipment & Materials

See the table below for equipment and materials referenced in this procedure:

Description	Part Number
Galaxy™ disposable sled	H749A70200
MO Disk	H749A70310
VCR Tape	08803-001
CD-R Disk	H749A70320
Field Service Report	07651-001
Printer Paper	H749A70350
Catheter Simulator	H749054080010

Prior to Testing

1. Log the serial numbers of the **Galaxy™ System** and MD5 on a Service Report or checklist (data sheet follows this section).
2. Remove the **Galaxy™ System** covers and back panel screws. Drop the back panel. Visually inspect all cables and connectors. Re-secure if necessary.
3. Dust & clean the PC as necessary using a vacuum and/or dry compressed air.
4. If the Overhead Monitor Switchbox (OMS) is utilized, connect the **Galaxy™ System** to the OMS using the Lemo®-Lemo® cable. Used stored x-ray images for testing purposes.

Functional Test

1. Power up **Galaxy™ System** and verify the system boots into the **Galaxy™ System** application.
2. Press **"Patient"** button, enter fictitious information in the Last Name and Patient ID fields, left click on **"Enter".**
3. Place the Catheter Simulator in the Motor Drive Unit (MDU) and place the MDU in a disposable sled.
4. Verify that the catheter simulator is identified properly.
5. Verify MDU LED display illuminates. Slide MDU forward and reset to zero.
6. Load the media; video tape, printer paper, blank CD-R (may use DVD+RW if **Galaxy™^{2}**) and MO disk (if applicable).
7. Press **"IMAGE"** and **"PULLBACK"** buttons on the **Galaxy™ System** control panel, press **"LONGVIEW"** button to switch to LongView™ display mode.
8. Verify Digital recording active.
9. Verify VCR recording active.
10. Verify fluoro test video is present next to the tissue ball in the LongView™ display mode (if OMS utilized).
11. Verify simulator image is acceptable.
12. Verify MD5 pulls back in the sled.
13. Verify that when pressing the Overhead monitor button on **Galaxy™ System** the OMS Roadmap video out toggles between the **Galaxy™ System** video and the fluoro test video (if OMS utilized).
14. Press **"IMAGE"** button to stop pullback, recording, and imaging.
15. Create/Select **"Run 2"** and press **"IMAGE**" on the MDU only.
16. While imaging, press or turn every control knob / slide / button on the Top Deck Control Panel.
17. Verify knobs and slides are secured to their posts.
18. Verify **Galaxy™ System** user functions and imaging parameters respond correctly to controls when adjusted.

    Note: There is no response for measurement functions, depth, digital playback when imaging and pulling back.

19. Press **"IMAGE"** button on the MDU to stop.
20. Double click on the Run 1 tab to load the data previously recorded.
21. Use the 'jog-shuttle' and digital Play control on the **Galaxy™ System** control panel to verify that the digital playback functions properly and that recorded audio can be heard during playback.
22. With a still IVUS image displayed, left click on the image field, draw one distance and one area, verify manual measurements can be performed (accuracy is not tested).
23. Press **"Trace Assist"** button on the **Galaxy™ System** control panel and verify a TraceAssist™ border is detected.
24. Press the **"Print"** button and verify printer functionality.

25. Use the VCR ‘jog-shuttle’ to verify that VCR recording and playback function properly; image is centered and audio is heard.
26. Open File Manager, verify the ‘test’ Patient name, Vessel and Run(s) appear in the Disk View.
27. Select the MO drive (if applicable, otherwise skip), left click on **“Format”** to format the MO disk. Verify successful “Galaxy” format.
28. Select the CD-ROM drive, left click on **“Format”** to format the CD-ROM. Verify successful “Galaxy” format.
29. Select the **‘test’** file from the HDD, drag & drop to the MO drive (if applicable) and again to the CD-ROM. Verify data transfers to media.
30. Remove MO disk and/or CD-ROM from **Galaxy™ System**.
31. Delete the **‘test’** patient from hard drive in the File Manager list.
32. Reboot the **Galaxy™ System** and install the MO disk and/or CD-ROM.
33. From the MO disk and/or CD-ROM, drag & drop the **‘test’** patient data to the hard drive in the File Manager. Verify data transfers normally. Remove media and reboot the **Galaxy™ System**.
34. Double click on the **‘test’** patient now listed in the File Manager. Data should load. Verify cine drive playback is normal.
35. Test the UPS function, verify: the < 1 minute timer starts when system power cord is unplugged and the < 1 minute timer stops when system power is restored.
36. Verify that “Snooze” functions normally: While in the ‘snoozed’ state, the 8 minute timer begins when the system power cord is unplugged and the 8-minute timer stops when system power is restored.
37. Shut down the system using the **“Shutdown”** button (via software application), left click on **“Yes”** in the confirmation message box. Verify system shuts down completely using software.
38. Document results on the Service Report or Data Sheet.

GALAXY™ SYSTEM FUNTIONAL TEST CHECKLIST

System S/N _____MD-5 S/N _____Date_____

Location (Customer) _____ City, State _____

1. Dust & clean PC.		DONE ☐	N/A ☐
2. Simulator ID functional		PASS ☐	FAIL ☐
3. MDU LED display illuminates		PASS ☐	FAIL ☐
4. Digital record mode functional		PASS ☐	FAIL ☐
5. VCR record mode functional		PASS ☐	FAIL ☐
6. Fluoro test video is present	N/A ☐	PASS ☐	FAIL ☐
7. Simulator image acceptable		PASS ☐	FAIL ☐
8. MD5 pulls back in the sled		PASS ☐	FAIL ☐
9. Overhead button toggles x-ray monitor display		PASS ☐	FAIL ☐
10. Knobs and slides secured		PASS ☐	FAIL ☐
11. System and image respond properly to controls		PASS ☐	FAIL ☐
12. Digital playback functional		PASS ☐	FAIL ☐
13. Recorded digital audio heard during playback		PASS ☐	FAIL ☐
14. Manual measurements functional		PASS ☐	FAIL ☐
15. Trace Assist Functional		PASS ☐	FAIL ☐
16. Printer functions normally		PASS ☐	FAIL ☐
17. VCR record/playback functions OK		PASS ☐	FAIL ☐
18. Patient name, vessel & runs appear in file manager		PASS ☐	FAIL ☐
19. MO media can be Galaxy formatted	N/A ☐	PASS ☐	FAIL ☐
20. CD-ROM media can be Galaxy formatted		PASS ☐	FAIL ☐
21. Data records to MO drive	N/A ☐	PASS ☐	FAIL ☐
22. Data records to CD ROM drive		PASS ☐	FAIL ☐
23. Data transferred to cine HDD from remote media		PASS ☐	FAIL ☐

24. Transferred data plays back from cine HDD	PASS ☐	FAIL ☐
25. The 1 minute timer is functional	PASS ☐	FAIL ☐
26. 1 minute timer is disabled at restoration of power	PASS ☐	FAIL ☐
27. Snooze functions normally	PASS ☐	FAIL ☐
28. The 8 minute timer is functional	PASS ☐	FAIL ☐
29. 8 minute timer is disabled at restoration of power	PASS ☐	FAIL ☐
30. **Galaxy™ System** shuts down using software GUI	PASS ☐	FAIL ☐

TESTS PERFORMED BY _____ Date _____

(signature)

Problem Solving

Motor Drive (MD5) problems

Intermittent recognition of catheter(s)

1. Is the catheter seated properly? Verify. Carefully pinch the tapered end of catheter hub (beige colored piece) and pull outward slightly. The catheter should not budge. It is very difficult to remove the catheter hub once fully inserted into the MD5 and locked in place.

   Problem Possibility:

   Catheter will not seat properly into the MD5.

   Possible Cause:

   A. The catheter is not inserted fully or appropriately; e.g., dot to dot.
   B. The MD5 shaft may not be mating properly with the catheter hub slot/receptacle.

   Solution:

   If the MD5/catheter mating problem is suspected, the user should remove the catheter and press the Image button on the MD5 or **Galaxy™ System**. This will spin the MD5 motor shaft. When imaging is stopped, the MD5 shaft should have a different orientation. Reinsert the catheter and try again.

2. Is the catheter hub dry? Be careful during the prep. If wet, the wrong catheter Id. may be displayed.
3. Has another catheter been tried? May be catheter problem.
4. Before replacing the MD5, test away from the patient table and out of the clinical setting. Save the catheter from the case or use demo catheters to test.
   A. Insert catheter into the MD5.
   B. If the catheters cannot be identified consistently, replace the MD5.
   C. If the catheters are identified correctly, there still may be an intermittent problem. Gently press on the side of a catheter hub (like on the flush port extension) in opposite directions and see if the Catheter ID. becomes intermittent. The Cath ID. should be 'rock solid;' stable. If intermittent, replace the MD5. Do not perform this test with the Simulator, which is more stable and may not demonstrate a failure.
   D. If the MD5 identifies all test catheters successfully, suspect clinical application.

"Catheter Motor Overload" (error message)

1. This message may appear 'once and awhile' and is normal whenever the catheter rotation is severely restricted (as with a NURD situation). Nevertheless, the appearance of this message should be infrequent. Check for application or catheter issues; e.g. catheter kink, tortuous calcified vessel, Touhy-Borst valve too tight, catheter hub not seated properly in the MD5.

   Problem Possibility:

   Catheter is not seated properly into the MD5.

   Possible Cause:

   The MD5 shaft may not be mating properly with the catheter hub slot/receptacle.

   Solution:

   If the MD5/catheter mating problem is suspected, the user should remove the catheter and press the Image button on the MD5 or **Galaxy™ System**. This will spin the MD5 motor shaft. When imaging is stopped, the MD5 shaft should have a different orientation. Reinsert the catheter and try again.

2. If the message appears very frequently there is a hardware problem that needs to be resolved. Most likely the MD5 will need to be replaced. Following the failure of replacement MD5's to eliminate these error messages, a Field Service visit may be required.

"Catheter motor speed out of tolerance" (error message)

1. When this message appears (usually) there is 'no problem' with the system's performance. Image quality is not affected and pullback performance is not compromised. The MD5's activity is monitored by software and based on tolerance specifications that (in retrospect) were too stringent. As a result, 'alarms' (the error message) occasionally go off unnecessarily. This problem has been resolved with a firmware update to the VME software. Field Service is required to install the software. If unsure of your system's version, email or call Fremont Technical Support for information.

EMAIL: ivus.techsupport@bsci.com
PHONE: AT&T (800) 949-6708

2. If the message appears and the latest firmware has been installed, replacement of the MD5 should conclusively resolve this issue.

MD5 will not pullback

1. The display may indicate a normal incremental (.5mm/sec) pullback as if it is pulling back, but the MD5 will fail to pullback if the MD5 is not seated properly in sled. Check both sides of the MD5/sled interface! Do not rely on the lit (MD5) LED display alone to determine whether the MD5 is seated properly.
2. Error message ***MDU Clutch Disengaged - Pullback Stopped***. The clutch lever that the user squeezes to allow the MD5 to slide back & forth in the sled is physically stuck.
   a. Try giving the clutch lever a few hard squeezes. Sometimes it will pop out.
   b. Otherwise, replace the MD5.
3. Error message ***MDU Pullback Motor Overload - Pullback Stopped***
   a. Most likely the sterile bag is caught up in the sled gear. Verify proper bagging technique. Slide back and forth once following insertion of the MD5 into the sled prior to pullback.
   b. Defective sled is a possibility; try another.
   c. Catheter restriction (Touhy-Borst too tight?) may also cause this message to appear.
   d. Replace MD5 if the problem is reoccurring and the aforementioned suggestions have been ruled out.

No image, catheter Id. is correct and stable, no error messages appear

1. Try another catheter or check with Simulator. Still no image? Then . . .
2. Reboot the **Galaxy™ System**. Still no image? Then . . .
3. Replace the MD5.

Dark images

1. Insure catheter is seated fully in the MD5 and that the Cath Id. is stable.
2. Flush the catheter or try another.
3. Reboot the **Galaxy™ System**.
4. Replace the MD5 if the symptom is reproducible.

Note **Galaxy™** instruments: If the MD5 is "started" within two seconds of the catheter insertion, the result is a weak image for that catheter. This often happens 'accidentally' by the user who bumps the start button at the MD5 while inserting the catheter. The solution is to stop imaging, then start again and full gain should be restored. **Galaxy™²** instruments are not problematic in this regard.

Galaxy™ System console problems

No video on the display screen when powered up

1. If everything else powers up (VCR, printer, fans) and the display screen is blank, call Tech. Support @ (800) 949-6708.
2. If the system is completely powerless, check the fuses in the back and/or test again at a different A/C outlet.
3. Be aware that some 'brand new' **Galaxy™ System**'s just out of the crate have experienced a wide range of anomalous problems that have occurred when initially powered up. Those 'anomalous' issues were resolved by plugging the system in for a couple of hours prior to use again. Depleted U.P.S. batteries are suspected as cause.

Problem Description:

Pre-mature failure of the UPS battery.

Cause:

User does not keep the **Galaxy™ System** plugged into A/C power at all times. If the **Galaxy™ System** is unplugged or 'stored' at a time when the when the UPS battery is in a 'less than fully charged' condition, battery damage may occur. The manufacturer of the UPS, American Power Conversion, states this:

> *A discharged battery, needs to be recharged within 72 hours of the discharge to avoid permanent battery damage. Storing a UPS with the battery connected can cause permanent battery damage within a few days to a week. Allowing batteries to stand for long time after a discharge without recharging will cause plate "sulfation." Sulfation is the formation of large crystals or "hard" lead sulfate on the battery plates. Excessive sulfation of this kind is difficult to reduce and may cause premature damage (i.e. overheating or inability of the battery to retain charge). All APC® UPS's protect their batteries against over-discharge, but, as implied above, the storage life of the battery will be shortened relative to the amount of charge removed.*

Solution:

Keep the **Galaxy™ System** plugged into A/C power at all times. If the instrument must be stored and away from A/C power, charge the **Galaxy™ System** (UPS) for at least 24 hours prior to storage.

Error messages following boot process or during the application

Examples: Internal sub-system failure, DAQ or NI-DAQ or VME Watch Dog / Dog Bark

1. Insure the **Galaxy™ System** UPS is fully charged (see section above). Minimally, leave plugged in for two hours prior to using the **Galaxy™ System**. Full battery charge usually takes 24 hours.
2. Insure MD5 Lemo® connector is plugged in all the way at the back of the **Galaxy™ System**.
3. Reboot **Galaxy™ System**. Error messages still present?
   a. Make sure that the UPS is OK and can hold a charge; test "snooze" functionality for 8 minute timeout. Early shutdown indicates a defective or uncharged UPS.
   b. If Biomedical Technician help is available, ask them to reseat the VME circuit boards. Check connections to the UPC Controller/A/C Distribution boards.
   c. Call Tech. Support @ (800) 949-6708 for assistance.

Printer problems

Description*:* Paper cuts one sheet at a time and falls on the floor.

Solution: This is the default setting for **Galaxy™**. **Galaxy™²** does not automatically cut. If undesirable, notify Field Service (800) 949-6708 and a Field Service Engineer (FSE) can reconfigure the **Galaxy™** printer software to 'paper-feed' during his next visit to the account.

Description*:* When print is selected an error message appears saying "Printer not found."

Solution: Most likely, the Mitsubishi printer alarm light is on. This is usually caused by **Galaxy™** being placed in 'snooze' mode (or powered down) while the printer is still trying to print. Once this occurs, rebooting **Galaxy™** will not reset the printer. To extinguish the alarm light: (1) take the printer off-line (2) press the paper feed / cut button (which it will do, paper feed and cut), then (3) place back on-line.

Description*:* Images are washed out and/or blurry.

Solution:

1) Paper is installed incorrectly.
2) Paper is old/damaged.
3) Wrong paper is being used.

Note, use only: Mitsubishi K65HM in the **Galaxy™**
Sony UPP-110S in the **Galaxy™²**

Description*:* Print starts to come out, then the alarm light comes on and stops / or print comes out crooked.

Solution: There is printer paper (usually small pieces) stuck on an inside roller, most likely the result of a previous paper jam. Clean away all paper from the inside roller. Note: This is not an easy task. Using a small jeweler's screwdriver

may help. All pieces of paper must be removed. Never use an alcohol solution to clean the rollers.

Note: If the Mitsubishi printer power is shut down and then restored using the on/off switch while **Galaxy™** is booted, the entire system needs to be rebooted to restore printer functionality. If **Galaxy™** is not rebooted and the "Print" button is pressed, an error message may appear saying; "Printer not connected." The printer should always be "on" when **Galaxy™** boots up.

VCR problems

Description*:* VCR playback quality is poor.
Comment: The **Galaxy™ System** takes hi-resolution computer video and converts it to standard (VCR) video so it can be recorded. When played back from the VCR, that standard, relatively 'low-line rate' S-Video is then up-scanned back to computer video for display on the **Galaxy™ System**'s monitor. Quality is lost in the process.

Note: Playing back the video tape on a remote VCR playback station (instead of using the **Galaxy™ System**) looks very good in comparison.

Description*:* Cannot read the alphanumeric from VCR playback.
Comment: Quality is too poor to read some of the small alpha-numeric. Try using the jog-shuttle and advance to another frame to reduce jitter.

Description*:* No VCR playback video – can hear audio but the **Galaxy™ System** display screen is blank (display may appear as a light shade of gray).
Solution:
1) Reboot the **Galaxy™ System**.
2) Check the VCR Video Input switch behind the hidden front door. Should be set to "S-VIDEO."
3) If Biomedical Technician help is available, check video cable plug at Extron Scan Converter on the back panel – plug falls out or loosens sometimes during shipment or aggressive instrument movement.

Description*:* VCR playback video is not centered during playback.
Solution: Extron Scan Converter needs to be replaced or the firmware updated. Field Service is required.

Description*:* When 'record' is selected, error message appears: "Internal sub-system not responding – VCR."
Solution:
1) Most likely, the write-protect tab is removed from the videocassette.
2) Check to see that the videocassette is installed.

Note: As with the printer, if the VCR is powered down (using the on/off switch) while the **Galaxy™ System** is booted, the entire system must be rebooted to restore VCR operation. The VCR should always be on when the **Galaxy™ System** boots.

Assorted issues

Issue: Message when loading data from CD or MO says "CD/MO cannot be removed until this run is **active**.
Comment: Should say "inactive." CD/MO cannot be removed until this run is INACTIVE. So, to remove the disk, select and load any *other* 'run' saved on the hard drive and make *that* run active. Then remove the media.

Issue: Audio and images become out of sync during digital playback, especially at the end of the record.
Comment: The way audio is digitally recorded is somewhat different than the way images are placed on the hard drive and the result is that they do not sync. up perfectly. Mostly this is not discernible but noticed more commonly at the end of long pullbacks.

Issue: While rotating the 2D 'cut-plane' line in LongView™ mode, when select (left click) is entered, the 2d image seems to jump a few frames and is not exactly where selected.
Comment: This is normal. The LongView™ information is displayed differently than the 2D image where there may be several frames of 2D imaging for only one line of LongView™ data. Thus, when the 2D slice is selected, **Galaxy™ System** determines the nearest representative LongView™ line of data and the 2D image may appear to 'jump' slightly.

Issue: When the **Galaxy™ System** boots up a DOS window appears with a message saying; "The operation was completed successfully."
Solution:

1. To remove the DOS window and use the **Galaxy™ System** normally, just click "OK."
2. The folders in the **Galaxy™ System** File Manager must always have at least one file in the folder (which is why there is always a 'Patient 1'). Often, when the user 'cleans up' a File Manager folder, folders are often deleted entirely (all at once, because it is easier to delete the folder rather than one file at a time). When a folder exists without a file (e.g.; DICOM, Screenshots), this symptom will appear. To resolve the above scenario, one needs to create a file in the empty folder. Usually this problem occurs when the Screenshots folder is erased. To resolve, just make a print. The next time the **Galaxy™ System** is booted the DOS window will be gone.

Chapter 6 DICOM

DICOM Configuration

Overview

This guide provides instructions for configuring the DICOM feature for a **Galaxy™ System** running software version 1.03, 2.01or 2.02.

Note: The user of this document must be proficient in MS-Windows networking configuration, and understand the requirements of the network utilized in the facility where this Galaxy™ System is installed.

The procedure is also best performed with the assistance of someone familiar with **Galaxy™ System** operation; otherwise, please refer to the **Galaxy™ or Galaxy™²** User's Guide for assistance with operation instructions.

Pre-installation

Before the **Galaxy™ System** DICOM installation is scheduled, we recommend that a person from the IT (Information Technology) staff of that institution enter the appropriate values in the "Assigned Entries" column of the "Networking Parameter Reference Chart" on page 104, and the "DICOM Parameter Reference Chart" starting on page 105. That information should then be forwarded to the BSC person in charge of the installation prior to the site visit. This will aid in the installation process, which cannot be completed without this information.

A DICOM Conformance Statement is available for **Galaxy™** and **Galaxy™²**, which defines its compliance with applicable parts of ACR-NEMA Digital Imaging and Communications in Medicine, DICOM V3.0. The **Galaxy™** BSC document number is 90047601. The **Galaxy™²** BSC document number is 90060910. If you need this document, please contact Boston Scientific.

Storage Server Considerations

The **Galaxy™ System** sends DICOM files up to 2 GB in size. When configuring the System, ensure that any Storage Servers set to receive files from the **Galaxy™ System** are capable of handling multiple files of this size.

NOTE: The **Galaxy™ System** is intended for network use in a DICOM Network only, and only to send DICOM files to a compatible Storage Server.

Viewing Station Considerations

Software used at DICOM Viewing Station can vary greatly in the ability to display IVUS images; and the information and imaging parameters that the **Galaxy™ System** provides in the DICOM files it exports. We recommend that the clinical users view sample **Galaxy™ System** DICOM files at the various Viewing Stations before or during this configuration process. Decisions on the settings for certain parameters such as image compression (if any), DICOM modality, and Screenshot inclusion may be affected by the results of such an evaluation.

The **Galaxy™ System** can also export DICOM files via its internal removable media disk drives for this evaluation. Contact your Boston Scientific Sales representative if you would like to obtain sample **Galaxy™ System** DICOM files on CD, MO or DVD media for evaluation purposes.

The DICOM Viewing Station must be able to display images with the following properties to display screenshots exported in the DICOM format from a **Galaxy™ System**:

- Photometric Interpretation: PALETTE_COLOR
- Size: 1280x1024
- Modality: Single-frame Ultrasound
- Image format: No compression

NOTE: The **Galaxy™ System** cannot display or import DICOM files.

Quick Reference Procedure

If you are not familiar with the topics in the following Quick Reference procedure, please proceed to the Detailed Information section.

1. Ensure that the **Galaxy™ System** is on (i.e., normal display), no operations are ongoing, all images have been archived, and that the archival media is removed.
2. Connect the **Galaxy™ System** to the network at the connector marked "LAN".
3. Move the pointer to the right border of the screen to reveal the main Menu Bar, select Imaging, then select the Params tab. Check that the Software Version displayed is 1.03, 2.01 or 2.02. If lower than 1.03, contact Boston Scientific.
4. Select File on the main Menu Bar, then select the DICOM Network tab.
5. Click the TCP/IP button. Enter the password (GAL2002), then click OK.
6. The standard Windows NT Network dialog box will be displayed. Ensure that the "(1) Intel 82557-based Ethernet PCI-Adapter" is selected where "Adapter" is

shown. All other settings in the Windows Network dialog boxes are per the requirements of the facility.

7. Once network settings have been completed, click OK in the Network dialog box.
8. Press the "Standby" position of switch on the rear panel to shut the System down, then re-start the System.
9. Reveal the main Menu Bar, select File, then select the DICOM Network tab.
10. Click the DICOM Admin button. Enter the password (GAL2002), then click OK.
11. Select the DICOMIT Config tab.
12. Click in the desired entry field, then make entries for AE Title and (optional) Station Name that are compatible with the network, then click the SAVE button. Other entries in the upper section are not used.
13. Remove any existing entries that are not applicable by clearing the AE_TITLE field, then clicking on the gray button on the left side of the DICOM Instruments table. When the whole row is highlighted, press the Delete button on the Keyboard.
14. See the "DICOMIT Configuration Reference" tables. A minimum of one Archive Device must be entered in the DICOM Instruments section (maximum ten).
15. Complete all entries, then click on any other row. The pencil icon will disappear and the entry is automatically saved.
16. Click on the DICOM Archives tab to bring that dialog box to the foreground.
17. Click the up-down arrows to set the correct number of Archive destinations.
18. Click in the AE Title field, delete existing entries if they are not applicable, then enter the "AE TITLE" (and the "Description") of the archive device(s).
19. Click the Save button.
20. Click the corresponding "Test" button. The **Galaxy™ System** will attempt to verify each DICOM association. If an "Association Made" message appears, a valid Association has been made with the DICOM device at that address.

    If an Association was not made, verify that all entries are exactly correct, observing case match as well. Also verify that related network cabling is correct, and the remote devices are on-line.
21. Click the EXIT button below the DICOMIT window to return to normal System operation. It is not necessary to re-start the **Galaxy™ System** for the DICOMIT settings to be implemented.
22. Reveal the main Menu Bar, then select File.
23. Select the Settings tab, then select the default values for DICOM file compression, modality, and Screenshot inclusion.
24. Select the DICOM Network tab, then highlight one or more DICOM Archival Destination. Click to toggle between select (highlighted) and deselect.

25. Place a check mark in the popup DICOM Archival Selection Dialog check box to automatically display the DICOM Archival Selection dialog box.
26. Refer to “DICOM Operations” following this section and in the **Galaxy™ System** User’s Guide for instructions on performing DICOM network transfers, to test for proper functioning of the System in the DICOM network.

Detailed Procedure

1. See the Windows NT Network Settings Reference table on page 104 and the "DICOMIT Configuration Reference" table on page 105. We recommend that you complete the entries in the "Assigned Entry" columns of these tables before continuing with this procedure. This information is usually provided by the network administrator for the institution.

2. Ensure that the **Galaxy™ System** is on (i.e., normal display), and that no operations are ongoing.

3. Ensure that all images have been archived, and that the archival media is removed.

4. See Figure 17. Connect the **Galaxy™ System** to the facilities network using an RJ-45 type connector inserted into the connector marked "LAN" on the Connector Panel (located on the lower rear of the System Console).

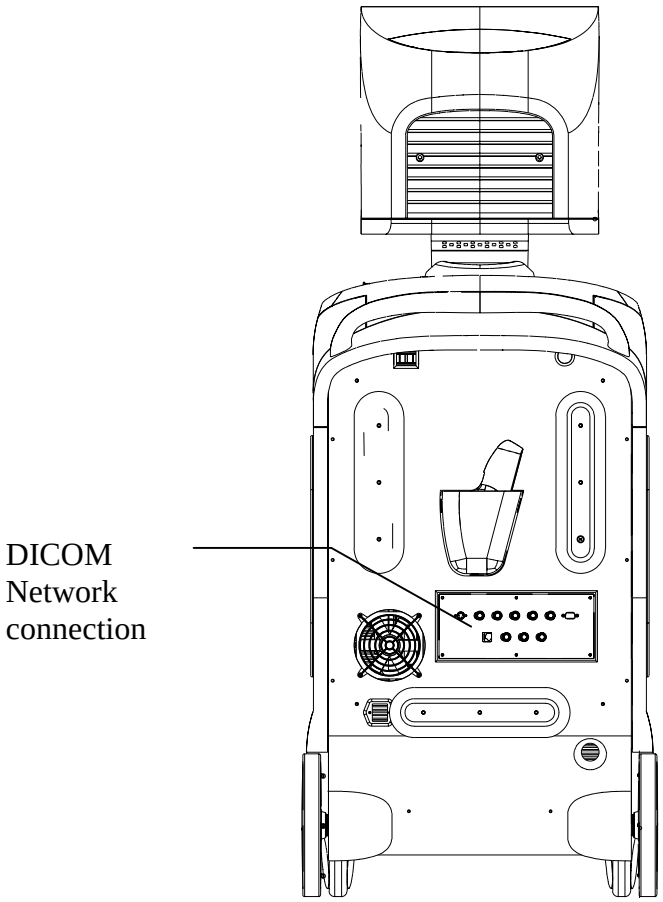


Figure 17 DICOM Network Connector Location

5. See *Figure 18*. Use the Trackball to move the pointer to the right border of the screen to reveal the main Menu Bar, then select Imaging.

Figure 18 Main Menu access and Imaging Menu Button

6. In the Imaging window, select the Params tab (if the Params window is not already in the foreground).

7. See *Figure 19*. Check the Software Version displayed to the right of "Active Preset Number". The software version must be 1.03, 2.01 or 2.02 higher. If not, discontinue this procedure and contact Boston Scientific for assistance.

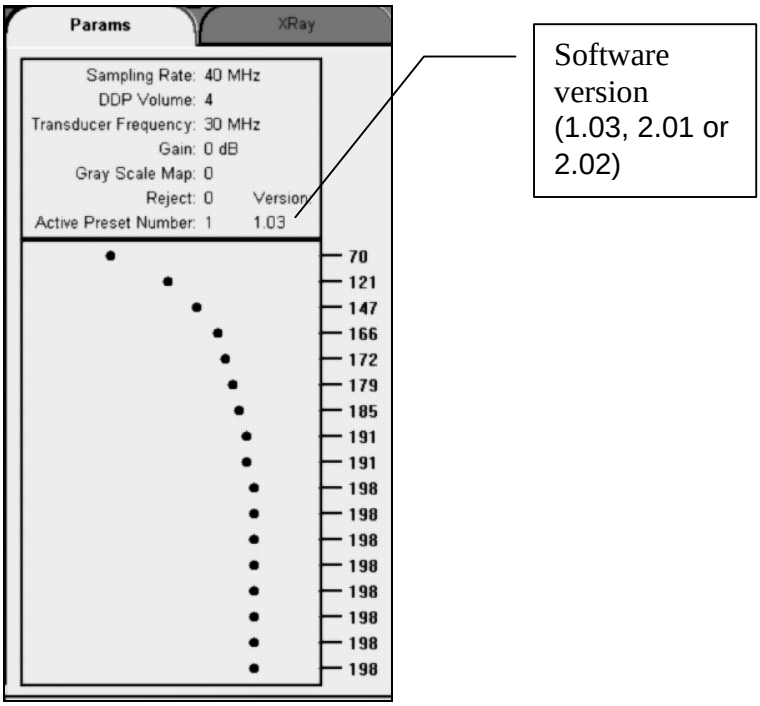


Figure 19 Viewing the installed software version

8. Use the Trackball to select File on the main Menu Bar, then select the DICOM Network tab (if the DICOM Network window is not in the foreground).

9. See Figure 20. Click the TCP/IP button. The "Enter Password" dialog box will be displayed. Enter the case-sensitive password GAL2002, then click OK.

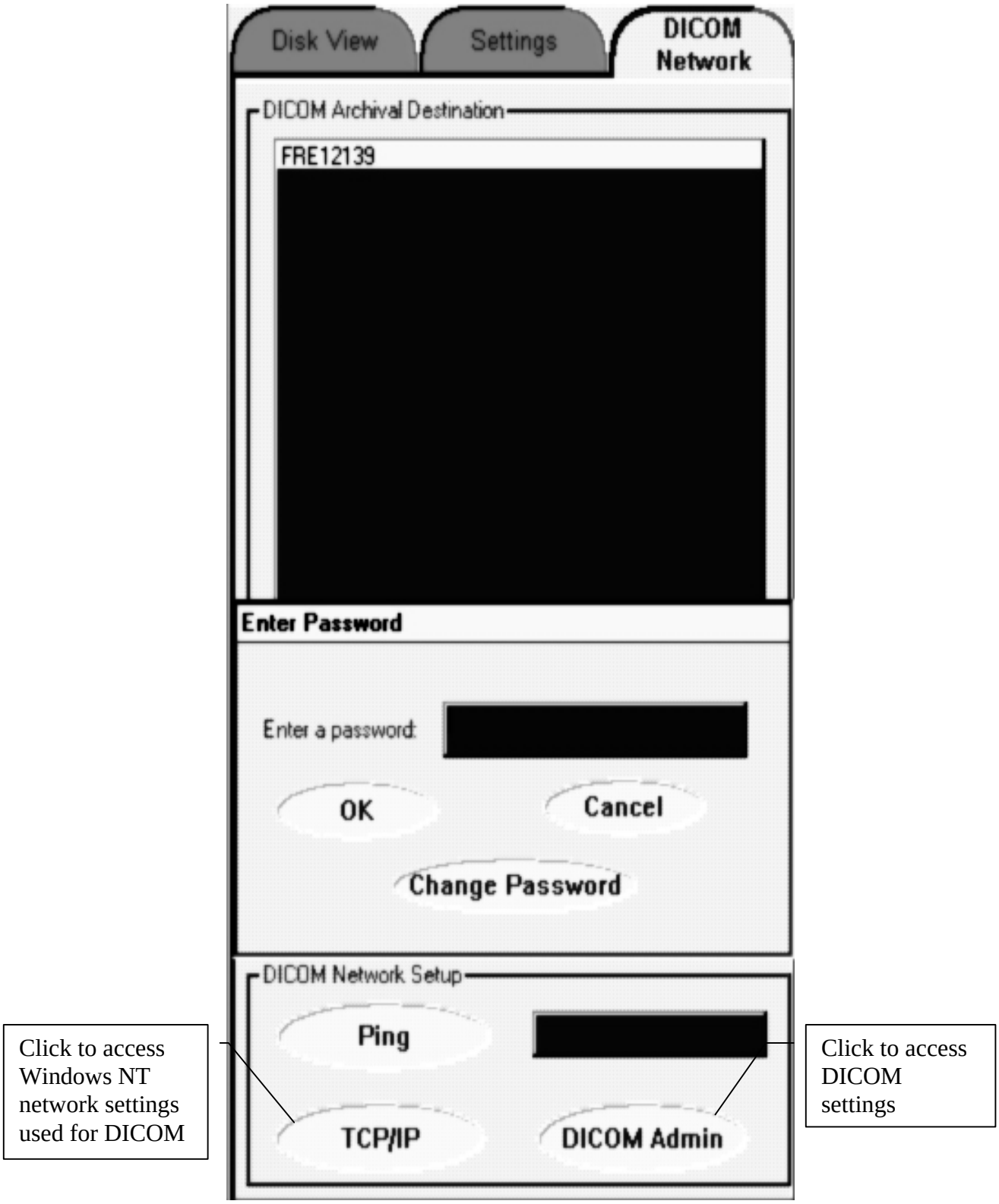


Figure 20 DICOM Network Window

10. See Figure 21. The standard Windows NT Network dialog box will be displayed.

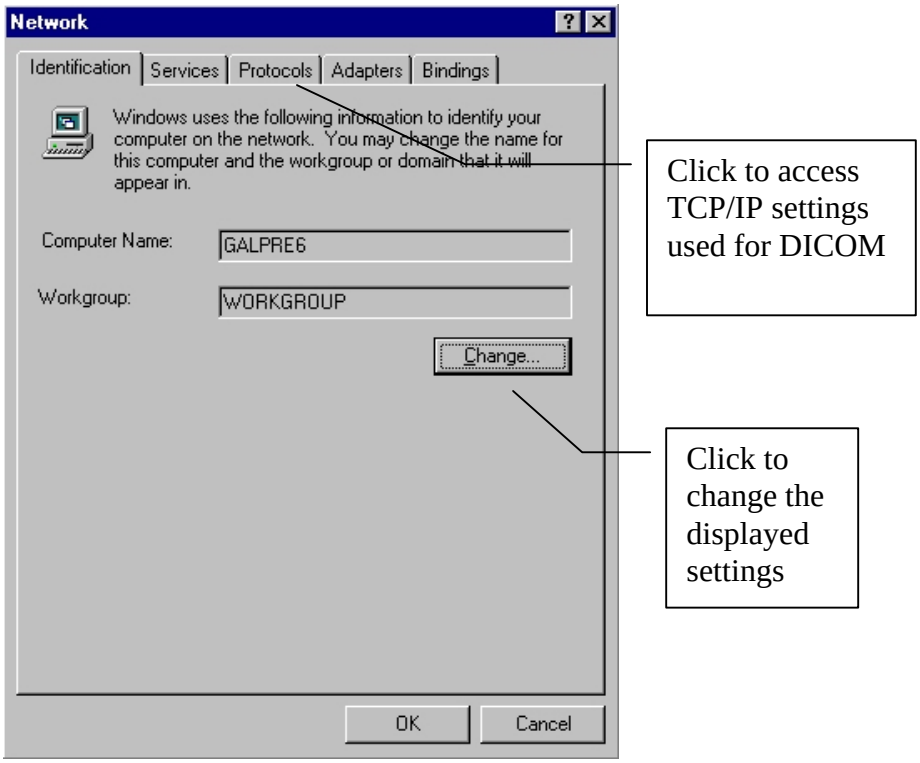


Figure 21 Standard MS-Windows Networking Dialog Box

Ensure that the "(1) Intel 82557-based Ethernet PCI-Adapter" is selected in all instances where "Adapter" is shown. This is the only setting that is **Galaxy™ System** dependent. All other settings in the Windows Network dialog boxes are per the requirements of the facility where this **Galaxy™ System** is being networked.

DICOM utilizes the TCP/IP protocol only. The following parameters are normally specified when setting up the networking parameters for DICOM:

- Computer Name – in the Identification tab (must be unique, can be changed from the default name provided)
- Workgroup – in the identification tab
- IP address – in Protocols - TCP/IP Properties, IP Address tab (or select "Obtain IP address automatically" if your network supports that feature)
- Sublet mask - in Protocols - TCP/IP Properties, IP Address tab, if an IP address is entered and your network requires this entry
- Gateway address - in Protocols - TCP/IP Properties, Gateway tab, if your network requires this entry

These entries are listed in the Windows NT Network Settings Reference table.

If you need further assistance in completing the settings in the Network dialog boxes, please refer to MS-Windows Networking documentation, or your network administrator.

11. Once the network settings have been completed, click OK in the Network dialog box, then press the “0” (Standby) position of the Power On / Standby switch on the rear panel to momentarily shut the System down.
12. Re-start the System using the “1” (Power On) position of the switch, then wait for the System to complete normal initialization.
13. Use the Trackball to reveal the main Menu Bar, then select File.
14. Use the Trackball to select the DICOM Network tab (if the DICOM Network window is not in the foreground).
15. See Figure 20. Click the DICOM Admin button. The “Enter Password” dialog box will be displayed. Enter the case-sensitive password GAL2002, then click OK.

See

16. *Figure 22*. Use the Trackball to select the DICOMIT Config tab (if the DICOMIT Config window is not in the foreground).

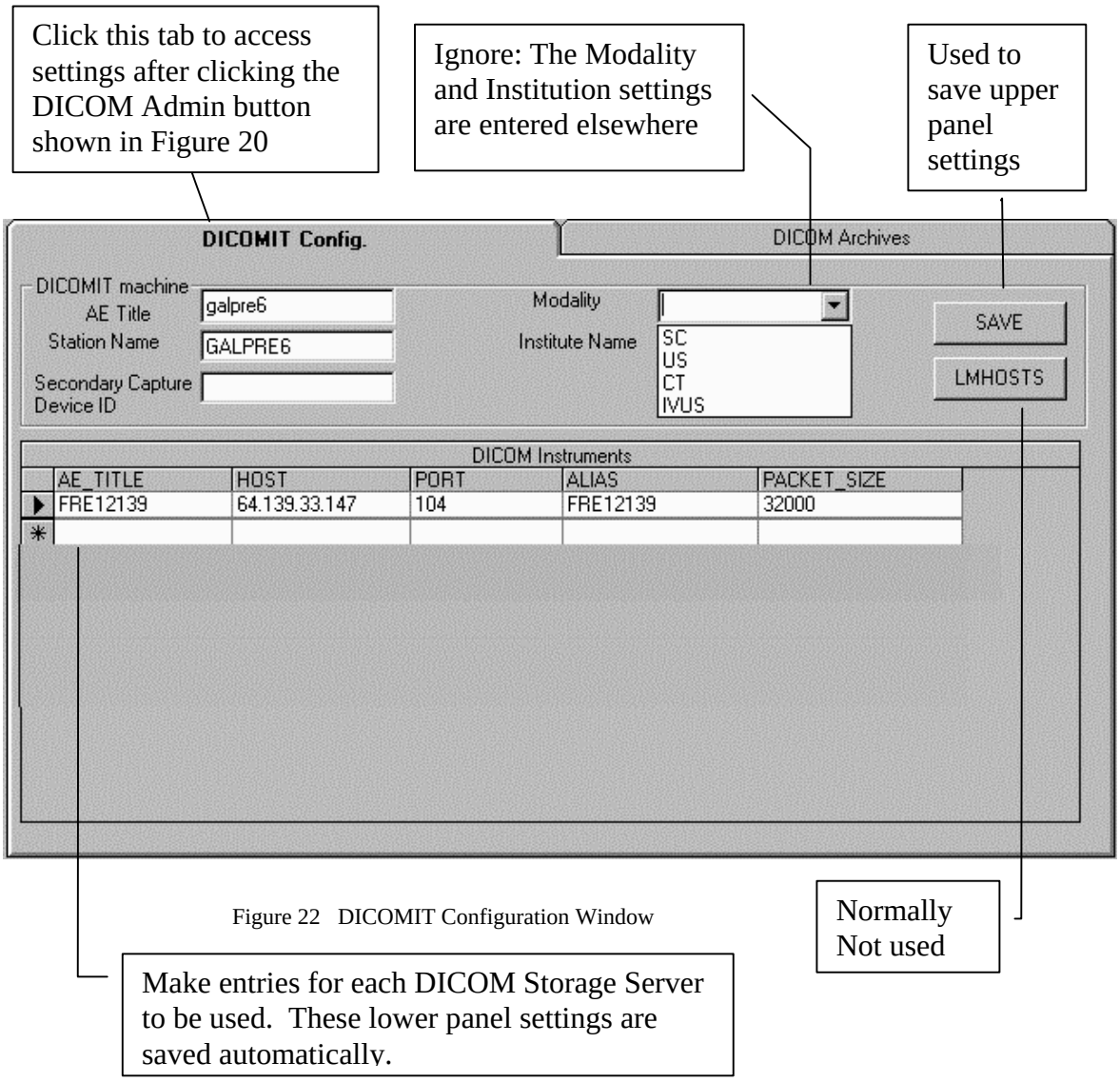


Figure 22 DICOMIT Configuration Window

NOTE: "DICOMIT" is an application used by the **Galaxy™ System** for parts of its DICOM communications capability.

17. There are two sections to this window. The upper section (labeled "DICOMIT Machine") determines how the **Galaxy™ System** will appear to other DICOM devices on your network. The lower section (labeled "DICOM" Instruments) determines how the **Galaxy™ System** will interact with other DICOM devices on your network.

18. In the upper DICOMIT machine section, use the Trackball to click in the desired entry field, then make entries that are compatible with your network for the following:

    - AE Title
    - Station Name (optional)

    See the "DICOMIT Configuration Reference" table.

Note: Station Name is optional. Secondary Capture Device ID does not apply to **Galaxy™ System**. The LMHOSTS button is not used, as the corresponding entries are established in the "HOST" column in the following DICOMIT Instruments section of this dialog box. Modality and Institution name are entered at a different location later in this procedure. Those settings here are not used.

- Click the SAVE button to save the upper section entries.

  At a minimum, one Archive Device should be set up in the DICOM Instruments section. No more than ten items should be entered. Only Archive Devices should be entered. The **Galaxy™ System** is not configured to communicate with any other types of DICOM devices. The Archive Devices configured must be capable or receiving multiple DICOM files of up to 2 GB. Due the slower processing speed of the **Galaxy™** (compared with **Galaxy™²**) when used with variable archive devices (servers), anecdotally, the slower **Galaxy™** instruments have mixed results when transferring files greater than 1GB.

- In the DICOMIT Instruments section shown in the lower part of the DICOMIT Config window, use the Trackball to remove any existing entries that are not applicable by first clicking in the AE_ TITLE field and then using the Delete key to remove that entry. Next, click the gray button on the left side of the DICOM Instruments table. When the whole row is highlighted, press the Delete button on the Keyboard.

- In the DICOMIT Instruments section, use the Trackball to click in the desired entry field, then make all five entries for <u>each</u> DICOM device with which the **Galaxy™ System** shall communicate (archive units):

    - AE Title
    - Host (the DICOM device's IP address)
    - Port
    - Alias
    - Packet Size (PDU maximum)

    See the "DICOMIT Configuration Reference" tables starting.

To Remove Data

Single cell - click on the entry. When it is highlighted, press the Delete button on the keyboard.

Entire row – First, click in the AE_TITLE field for that row, then press the Delete button on the Keyboard to clear that field. Next, click on the gray box on the left side of the AE_TITLE field. An arrow icon appears to the left and the row is highlighted. Press the Delete button again to remove all the data in this row.

Editing Entries

Click on the field to be edited, then type the desired entry.

Adding New Instruments

1. Click in the AE_TITLE field located next to the asterisk icon. Once you begin typing the edit, the asterisk will change to a pencil icon indicating that the record is being edited.

2. Click in each field to type the new value.

3. Complete all entries, then click on any other row. The pencil icon will disappear and the entry is automatically saved.

NOTE: The asterisk symbol in the left margin of the table indicates the row available for a new entry.

The DICOM Archives window provides setup and verification of a DICOM Association with the configured destinations. Setting up an Association is the configuration communication that takes place between sending and receiving devices. During this configuration communication, the devices establish what they do and do not support, thereby ensuring that neither attempts something the other does not support. A successful Association verifies that the DICOM connection is established with the remote system. This is much more comprehensive than a "ping" test.

NOTE: The following procedure can be also be used for testing communication with pre-established DICOM archives on the network.

To test the ability for the DICOM-configured **Galaxy™ System** to communicate with an existing DICOM Archive configured in the adjacent DICOM Instruments table, do the following:

22. See *Figure 23*. Click on the DICOM Archives tab to bring that dialog box to the foreground.

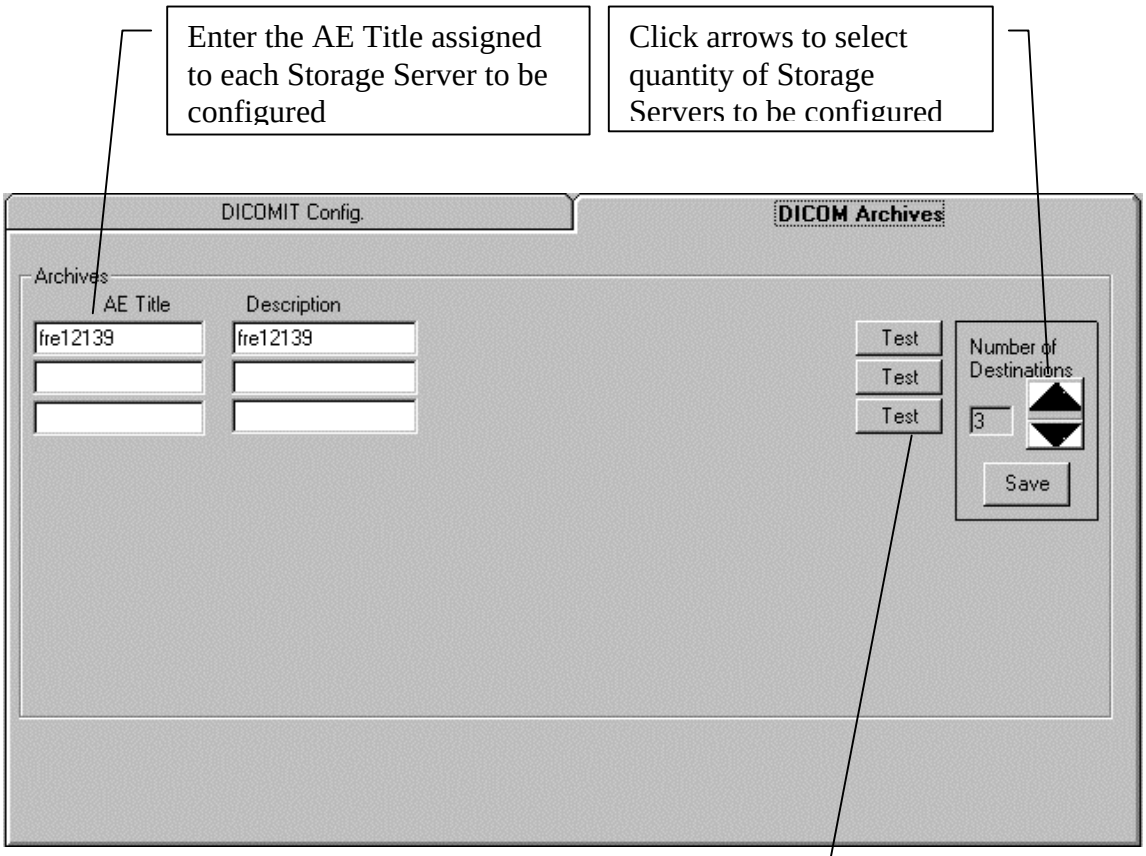


Figure 23 DICOM Archives Window used for Testing

23. Use the Trackball to click the up-down arrows to set the correct number of destinations per number of Archive locations entered in step above (excluding the entry for the **Galaxy™ System**).
24. Click in the AE Title field, delete any existing entries if they are not applicable, then enter the exact AE TITLE (and optionally, the "Description") of the archive device(s).
25. Click the Save button to store your entries.
26. Click the corresponding "Test" button. The **Galaxy™ System** will verify each DICOM association. If an "Association Made" message appears, a valid Association has been made with the DICOM device at that address.

If an association was not made:

1) Verify that all entries are exactly correct, observing case match as well.
2) Ping the Server.
3) Also verify that related network cabling is correct, and the remote devices are on-line.

Click the EXIT button below the DICOMIT window to return to normal System operation. It is not necessary to re-start the **Galaxy™ System** for the DICOMIT settings to be implemented.

Galaxy™ System DICOM Operator-Configuration

Settings

The following settings establish the default manner in which the **Galaxy™ System** handles DICOM operations. Although these settings can be changed by the user, they should be set to an initial state that is appropriate for the protocol used by the institution where this System is being set up.

NOTE: These settings establish the values used for most DICOM Network transfers, and establish the default values used for other DICOM conversions.

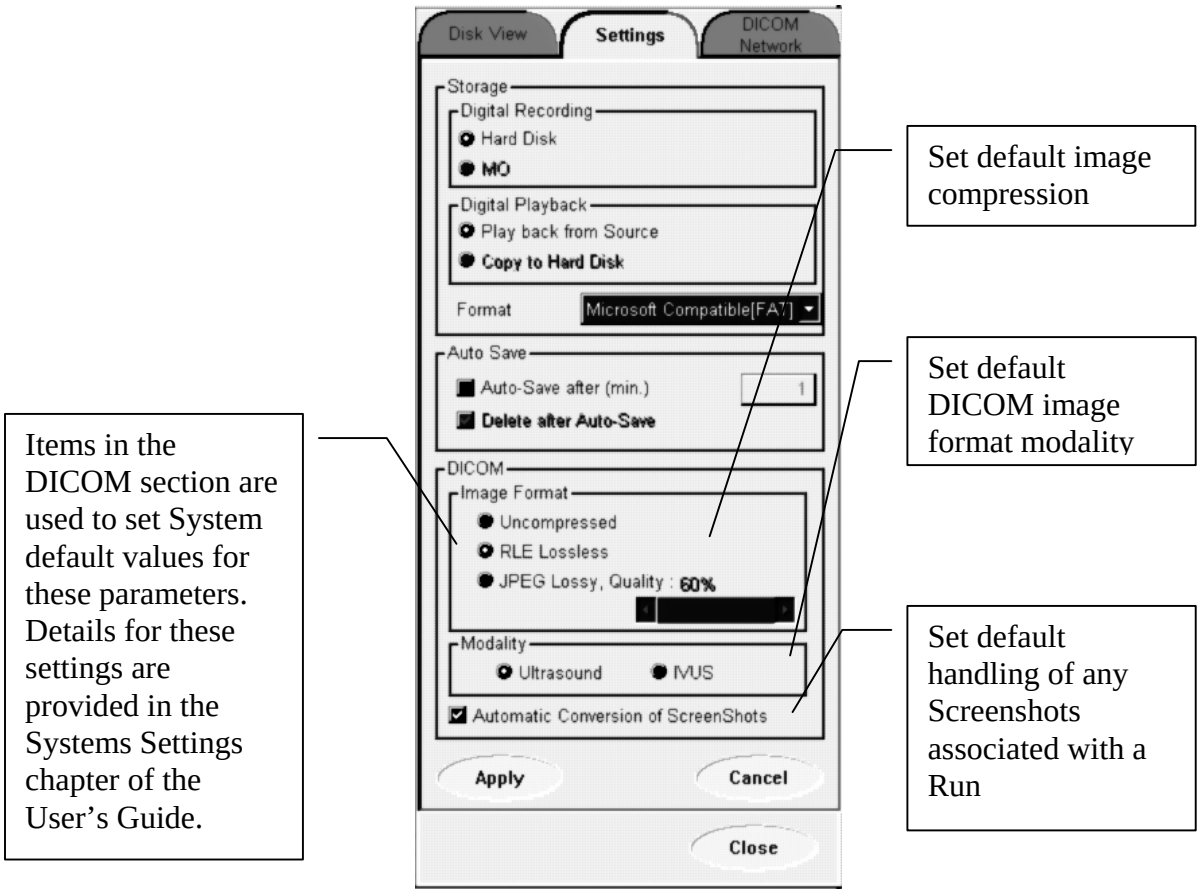


Figure 24 Settings Window showing DICOM Parameters

1. Use the Trackball to reveal the main Menu Bar, then select File.

2. Use the Trackball to select the Settings tab (if the Settings window is not in the foreground).

3. See Figure 24. Select the compression setting to be applied to images saved in the DICOM format by clicking Uncompressed, RLE Losses, or JPEG Lossy.

   If JPEG Lossy is selected, use the Trackball to click the arrows at the ends of the Quality setting to establish the desired value. Higher values result in higher image quality, and larger file sizes.

WARNING

JPEG compression reduces the spatial and grayscale quality of the stored image, even at the highest (100%) setting. This could impact the diagnostic quality of the images. Do not utilize this setting without approval from the institution.

PRECAUTION

Ensure that the institution's DICOM Viewing Stations are compatible with RLE Lossless compression before utilizing that setting.

4. See Figure 24. Use the Trackball to click either Ultrasound or IVUS (preferred) as the format for compiling the DICOM files for subsequent viewing. The IVUS selection provides more information; however, you should first ensure that this institution plans to use the IVUS viewing format on the DICOM Viewing Stations.

5. Each time that the Print button is pressed on the **Galaxy™ System** control panel, the current screen is printed, and a corresponding Windows bitmap file is saved in the Screenshots folder. If it is desirable to automatically convert each of these files to the DICOM format and transfer them with their associated Study, use the Trackball to place a check mark in the Automatic Conversion of Screenshots box (see Figure 24). Otherwise, clear this check mark (if present).

6. Use the Trackball to select the DICOM Network tab.

7. There must be at least one DICOM Archival Destination listed. Use the Trackball to highlight the archive that will be the initial setting. Multiple items can be selected. Click to toggle between select (highlighted) and deselect.

8. If it is desirable to automatically display the DICOM Archival Selection dialog box to allow the operator to select the DICOM Storage Server destination for

each Standard (non-automated) DICOM transfer, use the Trackball to place a check mark in the popup DICOM Archival Selection Dialog check box. Otherwise, clear this check mark (if present).

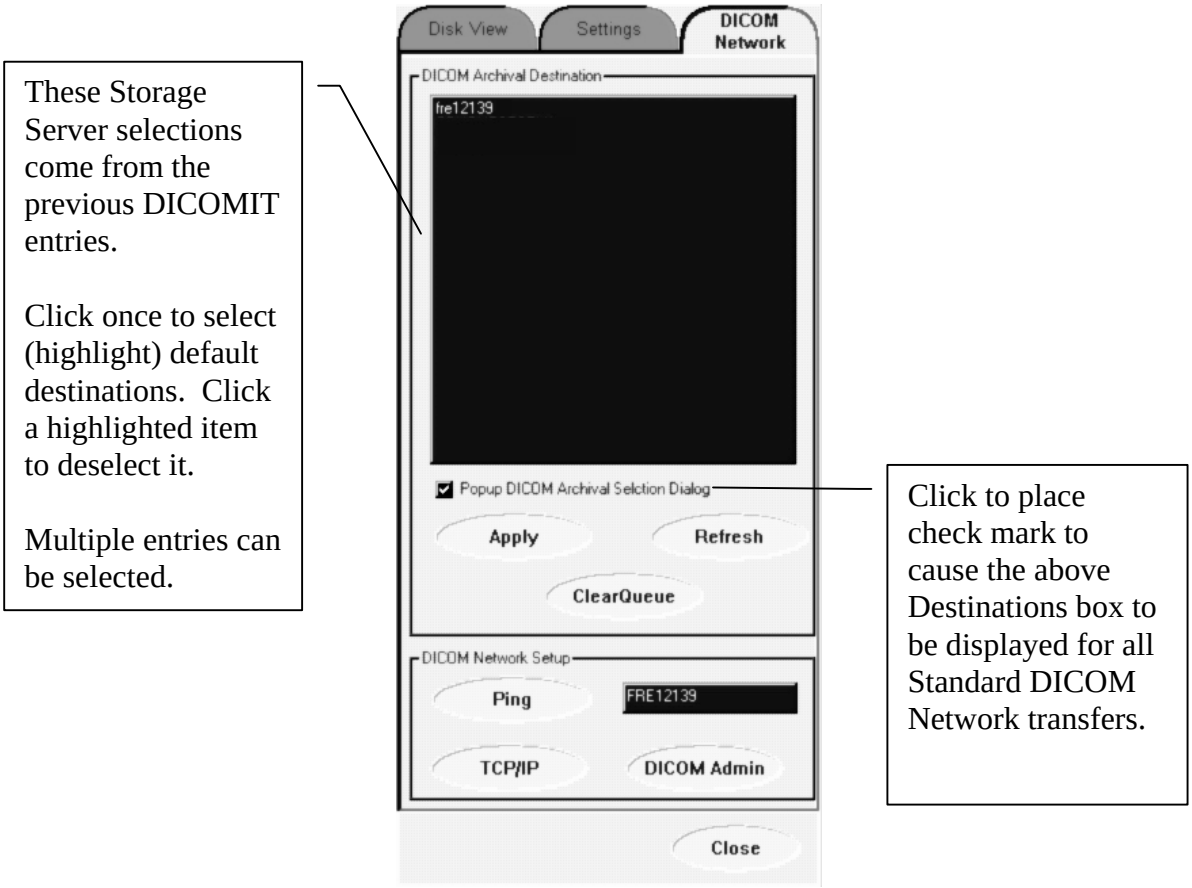


Figure 25 DICOM Network Window showing DICOM Parameters

9. If it is desirable to change the password used to access the TCP/IP settings and DICOM Administration settings, use the Trackball to select the DICOM Network Tab.

10. See Figure 20. Click the DICOM Admin button. The "Enter Password" dialog box will be displayed. Enter the case-sensitive password GAL2002, then click the Change Password button.

11. Enter the current password in the "Old Password" field.

12. Enter the case-sensitive new password in the New Password field, and re-enter it in the Confirm New Password field.

PRECAUTION

If the changed password is lost, it may hamper the ability to provide field support over the phone, and may require a site visit to remedy the situation.

DICOM Network Operation - Validation

We recommend that you refer to the chapter titled "DICOM Operations" in the **Galaxy™** or **Galaxy™2** User's Guide for instructions on performing DICOM network transfers, to test for proper functioning of the System in the DICOM network. In doing so, keep in mind that the **Galaxy™ System** can only export DICOM files to a properly configured DICOM Storage Server. After exporting some sample files, it is advisable to examine those files on the institution's DICOM Viewing Stations before considering the configuration process as being completed.

The **Galaxy™ System** can also export DICOM files to its internal removable media disk drives for evaluation at DICOM Viewing Stations. Files exported to removable media must be in the DICOM format to be viewable at DICOM Viewing Stations. Files in the native Galaxy format are not viewable at DICOM Viewing Stations.

Networking Parameter Reference

WINDOWS NT NETWORK SETTINGS REFERENCE			
Parameter	**Assigned entry**	**Description**	**Limitations**
Computer Name		The "Computer Name" assigned to this **Galaxy™ System** for networking.	Maximum 15 characters, no spaces, no slashes, case-sensitive. Must be unique in this network.
Workgroup		Identifies the group of DICOM devices to which the **Galaxy™ System** is assigned.	As assigned to this **Galaxy™ System** per the network administrator.
Protocols	TCP/IP (required for DICOM, others can also be listed).	Name of the method to be used for DICOM communications – pre-set by BSC to TCP/IP.	N/A
IP Address		Internet Protocol Address to uniquely identify this System.	As assigned to this **Galaxy™ System** per the network administrator.
Sublet Mask		Numerical mask used by the network for communication routing (optional per network).	As assigned to this **Galaxy™ System** per the network administrator.
Gateway		Address of Gateway device used to interconnect networks (optional per network).	As assigned to this **Galaxy™ System** per the network administrator.

DICOM Parameter Reference

DICOMIT CONFIGURATION REFERENCE FOR THE GALAXY™ SYSTEM			
Parameter	**Assigned entry**	**Description**	**Limitations**
AE Title (for **Galaxy™ System**)		Application Entity Title – should be the same as the "Computer Name" set in the Networking dialog.	Max. 15 characters, no spaces, no slashes, case-sensitive.
Station Name (for **Galaxy™ System**)		A "convenience" entry – optional – a "user-friendly" name – this entry not used for communications.	N/A
Secondary Capture Device ID	Not required for **Galaxy™ System**	A device that captures data via video digitizing.	N/A
Modality (for **Galaxy™ System**)		Type of imaging system – "IVUS" is the recommended choice for **Galaxy™ System** if compatible with the DICOM viewing stations, otherwise "US".	N/A – selected from pre-defined pick list (enter in **Galaxy™ System** Settings window of the File menu).
Institute Name		Name of institution where this **Galaxy™ System** is installed – not used for communications.	Max. 12 characters, no slashes (enter in **Galaxy™ System** Auto Entry window of the Tools Menu).

DICOMIT CONFIGURATION REFERENCE FOR ARCHIVES, ETC.			
Parameter	**Assigned entry ***	**Description**	**Limitations**
AE Title(s) (for Archives, etc.)		Application Entity Title for the Archive, etc.	Max. 15 characters, no spaces, no slashes, case-sensitive.
Host(s) (for Archives, etc.)		The **IP address** assigned to the Archive, etc.	Numerals and dot, as assigned for this DICOM device per the network administrator.
Port(s) (for Archives, etc.)	104	The port number for this DICOM device (per its AE Title) that it uses for DICOM communication.	104 is the standard port assignment used for DICOM.
Alias(es) (for Archives, etc.)		A "convenience" entry – optional – a "user-friendly" name, often the AE Title is used for this entry – not used for communications.	Max. 15 characters, no spaces, no slashes, case-sensitive.
Packet Size(s) (PDU) (for Archives, etc.)		The maximum packet size to be used by this Archive, etc.	Numeric integers only, range - 8192 to 1024000 (Industry default is 32000)

* Enter values for each DICOM device that will communicate with this **Galaxy™ System**.

DICOM Information

An application entity (AE) represents an entity such as an imaging system, image archive, printer, computer, etc. For example, if an imaging system is sending information to an archive, that imaging system represents one application entity (example: AE 1) and the archive represents another (example: AE 2).

An AE is presented by an AE Title, by which it identifies itself to other devices when communicating. AE Titles must be unique within the network used for DICOM. The AE is also assigned a unique Internet Protocol (IP) address and access port number.

There are no limitations on numbers of archives, but it is recommended to use no more than 10, due to system resources consideration. Any default entries listed in the DICOM Instruments section must be deleted and replaced to configure appropriate devices for your system.

Terms	Descriptions
AE	Application Entity; a software process that implements DICOM. Most implementations use multiple *AE's* when implementing multiple *Service Classes*. Requires a unique identification "AE Title", typically set up during installation, by which AE's identify themselves at the application level.
Association	A connection between AE's for DICOM exchange. Duration of an association is undefined, but is typically specified in the DICOM Conformance statement of a device. It could last for the duration of exchanging a complete image study.
DICOM	Digital Imaging and Communications in Medicine standard.
Host	In this manual, refers to the IP address assigned to a local DICOM device.
IVUS	Intravascular Ultrasound.
Modality	Acquisition system such as a CT, MR, IVUS, US.
PDU	Protocol Data Unit, a packet with number of bytes in one package that is created at the DICOM lower level protocol, sent via TCP/IP.
Port	Port Number used for an IP address.
SC	Secondary Capture - capture of data via video digitizing. "Secondary" indicates that the resultant

	data is not the original.
SCU	Service Class User, a DICOM *AE* which functions as a client, or “uses” a service, i.e. for printing, storage, etc.
Secondary Capture Device	A device that captures data via video digitizing.
TCP/IP	Transmission Control Program/Internet Protocol.

DICOM Operations

This chapter explains the **Galaxy™ System** DICOM features available in software version 1.03, 2.01 and 2.02, and how to use them to store **Galaxy™ System** IVUS procedures in DICOM format on the System's internal disks or over a DICOM network

It is assumed that you are familiar with DiskView's File Manager operation (explained in the User's Guide). If DICOM networking is to be used, it is assumed that the **Galaxy™ System** has been properly configured into that network. Refer to **Galaxy™ System** DICOM Configuration previously described in this chapter.

NOTE: The DICOM feature provided in **Galaxy™ System** software version 1.03 and higher complies with applicable requirements of the DICOM 3.0 standard.

Overview

The **Galaxy™ System** provides conversion of IVUS procedures performed on the System into DICOM (Digital Imaging and Communications in Medicine) formatted multiple frame series of images, or single frame images. The **Galaxy™ System** DICOM-formatted images are intended for viewing off the System (only), at Viewing Stations capable of displaying images in the DICOM IVUS or ultrasound modality.

NOTE: The term "transfer" is used to indicate the combined operation of converting the Galaxy-format image(s) to the DICOM 3 format, and then moving that DICOM file to the designated destination (DICOM Network, or a **Galaxy™ System** internal disk drive).

DICOM Capabilities

The **Galaxy™ System** can store the images it converts to DICOM format on its internal disk drives (System Hard Disk, MO, CD-R, DVD+RW). Additionally, if the **Galaxy™ System** has been configured into a DICOM network, it can also store DICOM-formatted images to Storage Servers on that network, either on an immediate basis, or from a queue on a scheduled basis.

When IVUS Runs are converted to DICOM format, several options are available:

Frame Range Selection – specifying the first and last frame in a Run for DICOM storage (optionally storing a subset of a Run)
Image Compression – none, lossless, or higher "lossy" compression
DICOM Modality Format – Ultrasound or IVUS
Screenshot Inclusion – Screenshots created from the selected Run can be included as a DICOM image file.

NOTE: Bookmarks are not supported in **Galaxy™ System** DICOM IVUS or ultrasound files. As an alternative, you can press the Print button in the **Galaxy™ System** control panel at each desired Bookmark, which will store a single frame image of that point in a Run as a "Screenshot". These Screenshots are associated with the Run and can also be converted to a single frame DICOM ultrasound-format image.

The System will prompt for entries for the options listed above when a single Run is copied to the DICOM folder or an internal System disk drive. In such cases, the System can also display that Run to allow easy selection of the range of Frames to convert, and creation of Screenshots for selected Frames. For other DICOM operations, the System applies user-selectable default values for these options (for Frame Range, all Frames are included).

DICOM Limitations

The **Galaxy™ System** offers important imaging features for review and analysis of IVUS images that are not supported by the standard DICOM 3 specification, such as LongView™, TraceAssist™, and Bookmarking. **Galaxy™ System** images converted to the DICOM format cannot be restored to the Galaxy format. If **Galaxy™ System** features like these are important to you, we recommend that you also store the images in Galaxy format. Doing so will allow you to continue to use the specialized **Galaxy™ System** features on Galaxy-format images, and also allow you to compare images from other procedures performed on a **Galaxy™ System**.

The **Galaxy™ System** does not read or receive images or data from the DICOM network. It is not possible to view DICOM files on the **Galaxy™ System** using software version 1.03 or higher.

Screenshots transferred to DICOM are always converted to the DICOM *Ultrasound* modality, as the DICOM IVUS modality does not support single frame images.
Normal System use is suspended during the conversion process, and all controls except the Cancel button in the DiskView window are disabled. If Cancel is selected, you will have to re-select unprocessed files for transfer at a later time.
There is no "Delete after Archive" function for any **Galaxy™ System** archival method. If deletion of the source files is desired, use normal System procedures to delete those files after the archive has successfully completed.

DICOM Network Operations

A Patient's IVUS procedure (Vessel(s) and Run(s) and Screenshots) can be converted to DICOM and stored to networked DICOM Storage Servers when the **Galaxy™ System** has been configured into a DICOM network.

NOTE: Configuring the **Galaxy™ System** into a DICOM Network is explained in the "DICOM Configuration Guide", H749A70630, and in the beginning of this chapter. The individual settings used for that configuration are explained in the "System Configuration Settings" here and in the User's Guide.

Standard DICOM Network Transfer

The Patient or Vessel or Run is copied to the DICOMNET folder in the DiskView window. It is immediately converted to DICOM format and then queued to be sent to the selected (or default) Storage Server(s).

Alternatively, an individual Run (only) can first be copied to the DICOM (not DICOMNET) folder. The System will then automatically display the DICOM Export dialog box, allowing you to view that Run and individually specify the Frame range, image compression, DICOM modality, and Screenshot inclusion settings for that Run's conversion. Following that, the Run is immediately converted to DICOM, and then must be copied to the DICOMNET folder, where it is queued for immediate transfer to the DICOM network.

The Standard DICOM Network Transfer method can offer greater flexibility than the automated method below (particularly when the "DICOM folder to DICOMNET folder" technique is used), but requires more user input to transfer the files, and may delay normal use of the System while the files are being converted to the DICOM format. Because System use is suspended during a DICOM conversion, it is only possible to select one Patient / Vessel / Run at a time for conversion, except in the case of Automated Transfers.

Automated DICOM Network Transfer

Patients, Vessels, and or Runs are simply right-clicked in the DiskView window to pre-select them for eventual conversion to DICOM format and transfer to the default DICOM network Storage Servers, using default conversion settings. This allows you to pre-select a number of items for DICOM transfer over a period of time without impacting normal System use.

Once the desired items are selected, the Set Auto Archival menu item is clicked and a dialog box is displayed prompting for a (optionally delayed) start time, then the transfer process starts either immediately or after the scheduled delay time.

This method's pre-selection and scheduling features can be used to avoid delays in normal System usage while files are converted to DICOM.
The following table summarizes the differences between Standard and Automated DICOM Network Transfers, to aid you in selecting the method that best meets your needs:

COMPARISON OF STANDARD AND AUTOMATED DICOM NETWORK TRANSFERS		
	Standard	**Automated**
Item pre-selection to aid workflow	No	Yes
Scheduled conversion and transfer	No	Yes
Impact on normal use	More	Less
Ease of use	Less	More
Flexible archival destination options	Yes	No
Automatic queue reschedule *	No	Yes
Frame range, compression, DICOM Modality, and Screenshot inclusion selection **	Yes **	No

* If normal System use is initiated and the Automated Transfer queue has not yet started to process.

** Individual Runs only, via DICOM folder to DICOMNET folder

Standard DICOM Network Transfers

To use this method, the desired Patient, Vessel, or Run is manually copied to the DICOMNET folder using normal DiskView Copy and Paste or Drag and Drop operations. This DICOM conversion method handles studies selected by Patient or Vessels differently than Runs.

By Patient or Vessel

When a Galaxy-formatted Patient or Vessel is copied to the DICOMNET folder, **Galaxy™ System** default values are used for image compression, DICOM modality (ultrasound or IVUS), Screenshot inclusion; and the full length of all related Runs are included. When a Patient is selected, all of that Patient's Vessels and their associated Runs are included. When only a Vessel is selected, all of the Runs for that Vessel are included.

The DICOM Storage Destination Dialog Box may be displayed (if the system is configured to do so), allowing selection of one or more of the pre-configured DICOM Storage Servers; otherwise, the preset default destination(s) are used. Once the Send button in this box is clicked, the selected Patient or Vessel and its Runs are immediately

converted to DICOM and then transferred to the DICOM Network; or converted and then queued for transfer if another transfer is in progress or the network is not available.

By Run

When the item selected for a Standard Transfer is a Run, there are two methods available. If the Run is copied directly to the DICOMNET folder, it is handled in the same manner as explained above. If it is desirable to change the default image compression, DICOM modality, Screenshot inclusion setting, or to transfer only a subset of the Run, then the Run can be copied to the DICOM (not DICOMNET) folder first. In such cases, the DICOM Export Dialog Box is then displayed, allowing selection of frame range (first through last frame number to be included), image compression (none, lossless, or lossy), DICOM modality (ultrasound or IVUS); and if related Screenshots are to be included. The Display Run button can be used to display the selected Run, to aid in selection of Frame range.

When the Export button is clicked, Run is immediately converted to DICOM using the specified settings. In order to transfer it to the DICOM network, it must be copied again, now from the DICOM folder to the DICOMNET folder. When this is done, it will be immediately transferred to the DICOM network, or queued for transfer if another transfer is in progress or the network is not available.

If the System must be used for imaging or playback during the actual time that item is being converted to the DICOM format (which typically takes 5 to 10 minutes), that process must be cancelled. Any files waiting to be transferred to the DICOM Network will be also cancelled, except for DICOM files currently in an Automated Transfer time-delayed queue that has not yet begun to be processed (explained below).

Automated DICOM Network Transfers

Selection

Galaxy™ System also offers a more automated conversion and transfer of DICOM files. To use this method, simply right-click on Patients, Vessels, and Runs stored in the **Galaxy™ System** Imaging Hard Disk (only), and they will be pre-selected for eventual DICOM transfer, using the system preset defaults for image compression, modality, and Screenshot attachment. The labels for the selected items will change to green text. When a Patient is selected, all of that Patient's Vessels and their associated Runs are included. When a Vessel is selected, the Runs for that Vessel are included. (In each case, Runs or Vessels that were automatically included can also be individually de-selected by right-clicking them). You can select (or de-select) items by right-clicking at any time that the System is not actively imaging, playing back a Run, performing an Auto Save, or doing a DICOM conversion (in all these instances, normal System use is suspended). Having items pre-selected (but not committed to the automated transfer queue) has no impact on System operations, including other DICOM operations. The pre-selection of items is not cleared when a DICOM operation must be cancelled to restore normal System operation.

Processing

Once desired Patients/Vessels/Runs have been selected, the DICOMNET folder is right-clicked and "Set Auto Archival" is selected from a pop-up menu. (If any items are already in the DICOMNET folder awaiting transfer, you will be prompted that they must be either processed first or deleted before you can establish the Automated Transfer queue). A dialog box is then displayed allowing selection of a delayed time for conversion and transfer, if desired. Finally, the Start Archive button is clicked; and then starting either immediately, or at the designated time, each selected file is converted to the DICOM format, and then transferred to the DICOMNET folder to be sent to the default DICOM Network Storage Servers. Only one Run is converted and then queued for transfer at a time. Until it is successfully transferred out to the DICOM network, any additional queued items are not acted upon.

If a time delay was selected, additional items can be added to the queue until processing of that queue begins, using the same process explained above.

If the **Galaxy™ System** is being used for imaging, continuous playback, or performing an Auto-Save when the selected delay time expires, the start time will automatically be re-set for thirty minutes later (repeated as necessary until transfer is complete or system is shut down). There is no need to cancel the Automated Transfer method in order to use the system; however, for best results, we recommend that you select a delay time that will cause the Automated Transfer to start during a time when it is unlikely that the system will be used. DICOM Network transfers can take from a few minutes to several hours, depending on several parameters such as:

Number of Runs
Length of those Runs
Compression selection
Network availability and throughput

Once the **Galaxy™ System** begins to process the Automated Transfer queue, normal system use is suspended. To add additional items at this point, or to regain normal system use, the Automated Network Transfer queue must be cancelled using the Cancel button in the DiskView window, and any remaining items will be deleted from that queue.

Once the Start Archival is clicked, the delay time cannot be directly changed. To set a new delay time, you must use the Clear All Queue function. (This does not de-select the previously right-click selected items). Next, use the Set Auto Archival command to re-set the Auto Archive time, etc.

NOTE: Items selected for Automated Transfers will not appear in the DICOMNET folder until after they are converted to the DICOM format, which is done one at a time; therefore, only one item selected for Automated Transfer will appear in the DICOMNET folder at a time.

The automatic rescheduling feature is only activated during active imaging, continuous playback, or during an Auto-Save operation. If the **Galaxy™ System** is unused momentarily and the time delay expires during that idle time, queue execution will begin immediately, and the cancellation method explained above must be used to regain normal use of the system.

The Standard DICOM Network Transfer method can be used to transfer individual items immediately, while the Automated DICOM Network Transfer queue is in a time-delayed state.

DICOM Storage on Galaxy™ System Removable Disk Media

A Galaxy-formatted Patient, Vessel, Run, or Screenshot can be converted to DICOM and stored on the System Hard Disk, or to appropriately formatted CD-R, DVD+RW, or MO media internal to the System. DICOM and Galaxy-formatted images cannot be stored on the same removable media surface. DICOM storage requires CDFS-formatted media for CD/DVD storage, or FAT-formatted media for MO storage. Only Screenshots in the Screenshots folder of the Imaging Hard Disk can be converted to DICOM format.

Items are automatically converted to DICOM format when they are copied to a drive containing removable media that has been pre-formatted for DICOM images (CDFS for CD.DVD, or FAT for MO disks). MO media must be manually pre-formatted to FAT; then any Galaxy-formatted Patient, Vessel, or Run copied to the MO Drive icon containing such formatted media will automatically be converted to DICOM.

The **Galaxy™ System** will automatically format new CD/DVD media to the required CDFS format if items are first copied to the DICOM folder for pre-conversion, and then copied to an unformatted CD/DVD disk. Otherwise, the CD/DVD media must first be manually formatted to CDFS; then Galaxy-formatted Patients, Vessels, or Runs copied to that media will automatically be converted to DICOM and stored on that media (without the necessity of first copying those items to the DICOM folder).

Capacities

The 700 MB CD-R in **Galaxy™** can store approximately 3,000 uncompressed Frames (about 1 ¾ minutes) of DICOM Runs. The 4.7 GB DVD+RW in **Galaxy™²** can store approximately 20,000 uncompressed Frames (about 12 minutes) of DICOM Runs. Each side of an MO disk (**Galaxy™** only) can store approximately 12,000 uncompressed Frames (about 6 ½ minutes) of DICOM Runs. Use of compression can significantly increase these numbers (three to four times is typical for RLE compression); however, since the amount of compression is dependent on image content, etc., it is impossible to accurately predict by how much. Each single frame Screenshot image uses about 1.25 MB of storage.

Method

To store DICOM files on removable **Galaxy™ System** media, the desired Patient, Vessel(s), or Run(s) are manually copied to the drive icon using normal DiskView Copy and Paste or Drag and Drop operations. This DICOM conversion method handles Galaxy-formatted Patients or Vessels differently than Runs.

By Patient or Vessel

When a Galaxy-formatted Patient or Vessel is copied to the drive icon, the default values are used for image compression, DICOM modality (ultrasound or IVUS), and Screenshot inclusion; and the full length of all related Runs are included. When a Patient is selected, all of that Patient's Vessels and their associated Runs are included. When a Vessel is selected, only the Runs for that Vessel are included.

By Run

When the item selected is a Run, the DICOM Export Dialog Box is displayed, allowing selection of Frame range (first through last frame number to be included), image compression (none, lossless, or lossy), modality (ultrasound or IVUS), and if related Screenshots are to be included. The Display Run button can be used to display the selected Run, to aid in selection of Frame range. When the Export button is clicked, the Run is immediately converted per these selections and then written to the removable media in that drive.

Because **Galaxy™ System** use is suspended during a DICOM conversion, it is only possible to select one Patient / Vessel / Run at a time for conversion, except in the case of Automated DICOM Network Transfers.

If the **Galaxy™ System** must be used for imaging or playback during the actual time that files are being converted to the DICOM format, that process must be cancelled. Any queue of files to be converted to DICOM will also be cancelled.

DICOM-related DiskView Items

When looking at the contents of a folder or disk containing DICOM files, the items are shown in a somewhat different manner, to accommodate DICOM nomenclature standards.

The following table summarizes the differences in DiskView between Galaxy-formatted and DICOM files:

DICOM IN DISKVIEW	
Galaxy format	**DICOM format**
Patient	Patient
Vessel	Study (per Vessel label)
Run	Images (per Run label), multi-frame DICOM images w/start-end frame
Screenshot	Image (per Run label), single frame

Items for Automated DICOM Network transfer can only be selected from the Imaging Hard Disk. If an item you need to transfer is at another **Galaxy™ System** location, use normal DiskView operations to copy it to the Imaging Hard Disk first, then proceed with the DICOM operation desired.

Screenshots for DICOM transfer can only be manually selected from the Imaging Hard Disk's Screenshot folder. It is not possible to copy items into that folder.

DICOM Folder

The DICOM folder is used to allow Galaxy-formatted Patient, Vessel, Run, and Screenshot files:

- Which will be converted to DICOM when the DICOM files are to be stored on a previously unformatted CD-R.
- (Runs only) to be converted using other than the default compression, DICOM modality, and Screenshot inclusion settings; and/or to select a subset of the full range of Frames in that Run for conversion.

- Which will be converted to DICOM format and then held on the System Hard Disk temporarily for future disposition.

NOTE: The **Galaxy™ System** Hard Disk has fairly limited storage for DICOM files, and this storage space is also needed during the conversion process; therefore, do not use this as an archival location or you will receive error messages requiring you to remove files to make working space available.

In all these cases, the DICOM folder is an intermediate point only. Once the files are converted to DICOM, they must be manually copied (which in this case is automatically a "move" operation) to the DICOMNET folder or a removable disk drive icon.

DICOMNET Folder

The DICOMNET folder represents the queue for all pre-converted DICOM files that will be transferred over the DICOM network. Items being transferred using the Standard DICOM Network Transfer method are manually copied to this folder from the DiskView tree or the DICOM folder. Their labels are listed in this folder until they are successfully transferred to the DICOM Network. When the Automated DICOM Network Transfer method is used (where Galaxy-formatted files are right-clicked to add them to a time-specified queue), those files are automatically placed in the DICOMNET folder one at a time, after they have been converted to DICOM. Until they are converted to DICOM, they are only shown in the DiskView tree, with a green label.

NOTE: Non-IVUS Screenshot files (e.g. Pre-Post screen, Report screen, etc.) cannot be copied to the DICOMNET folder.

If you click the DICOMNET folder to open it, queued items are shown until transferred, then its label is automatically deleted from the DICOMNET folder. If an error occurs, the Run label will change to red. You can double-click that label to display the error condition.

NOTE: Duplicate vessel names will be displayed in the DICOMNET folder if a patient or Vessels are copied to it more than once.

If you right-click the DICOMNET folder, a pop-up menu is displayed which can be used to:

- Assign previously right-clicked items (shown with green labels) to the Automated DICOM Network Transfer queue.
- De-select all previously right-clicked items (shown with green labels) – these have not yet been committed to the queue.
- Clear an existing queue of all unprocessed items, including those added to it via the Standard Transfer method (which are awaiting transfer because the DICOM Network is busy or not available).

The text label for DICOM items are color-coded to indicate their status:

Green – pre-selected items in DiskView awaiting assignment to the queue.
Blue – items in the DICOMNET folder that are actively being transferred.
Red – operation failed – double-click the item to view its status.

Color-coding is not utilized in the DICOM folder.

DICOM-specific DiskView Operations

Patient-related files in the Screenshot folder can also be converted to DICOM files using the same Copy and Paste methods described for Runs.

DICOM files cannot be copied to Galaxy-formatted media. Galaxy-formatted files cannot be copied in their native format to the DICOM network.

Galaxy-formatted files copied to media that has FAT or CDFS format will automatically be converted to DICOM and then copied.

DICOM files cannot be converted (restored) to the Galaxy format.

A DICOM Delete operation removes the selected item, and any lower level items associated to it; however, the related Patient information and any Galaxy-formatted image files are not deleted. DICOM items cannot be deleted while the **Galaxy™ System** is imaging, playing a Run; or from a finalized CD-R or write-protected media.

Export Settings

The **Galaxy™ System** default settings established in the DICOM Network window are applied to each conversion of a Run selected via Patient or Vessel, or by using the Automated DICOM Network Transfer method.

The DICOM Export dialog box is displayed whenever a single Run (not selected by Patient, Vessel, or Automated Transfer) is copied to the DICOM folder or a removable disk drive icon that contain media formatted to store DICOM files (explained above). It allows you to accept or modify the default settings, plus select a subset of the Run for transfer if desired.

These settings are summarized below.

Image Compression (Format)

The DICOM standard supports image compression to save storage space and reduce the time it takes to transfer files. RLE (Run Length Encoded) compression does not alter the image quality, but generally offers less compression than JPEG (Joint Photographic Experts Group) compression. All JPEG compression can degrade the spatial and grayscale quality of the stored image, even at the highest quality (100%) setting. This could impact the diagnostic quality of the images.

We recommend that you first determine your institution's policy on DICOM image compression before selecting a setting for compression. You may also want to ensure that your institution's DICOM Viewing Stations are compatible with JPEG or RLE compression before utilizing that setting.

If JPEG Lossy is selected, the DICOM Export dialog box provides a setting for the extent of compression applied. Higher values result in higher image quality, with correspondingly larger file sizes.

NOTE: Compression is not applied to Screenshots converted to DICOM format.

The following table provides some insights on the effects of compression on storage space required and storage time required. Keep in mind that the degree of compression possible is dependent on the content of the images being compressed; and that the time to copy the resultant file to its destination is dependent on the destination selected (e.g. network speed and availability, type of removable media, etc.

DICOM Processing EXAMPLE– 9000 Frame (5 minute) Run				
Output Format	DICOM Conversion time	Time to copy to destination	Total Time	Resultant File Size
Uncompressed	6.4 Minutes	12.2 Minutes	18 minutes	1978 MB
RLE Compression	6.1 Minutes	0.3 Minutes	6.4 Minutes	77 MB
JPEG with 75% Quality	9.0 Minutes	0.2 Minutes	9.1 Minutes	62 MB
JPEG with 25% Quality	8.5 Minutes	0.03 Minutes	8.6 Minutes	42 MB

NOTES:

- A 15cm (150mm) pullback (which is the maximum possible) will require about 5 minutes (9000 Frames) of recording at a 0.5 mm/sec. pullback rate (or 2.5 minutes at 1.0 mm/sec. pullback).
- Copy time listed is from the temporary conversion location to a destination on the System Hard Disk. Copy times will be greater to removable media, or network destinations.

DICOM Modality

The **Galaxy™ System** offers either Ultrasound or IVUS selections for the DICOM modality setting. Either will allow viewing of the IVUS Studies exported by **Galaxy™ Systems**; however, the IVUS setting provides additional features such as Pullback-related readings that are not supported in the Ultrasound selection. You may want to ensure that your institution's DICOM Viewing Stations are compatible with the DICOM IVUS Modality before utilizing that setting.

NOTE: Screenshots are always exported in the DICOM ultrasound modality, since the DICOM IVUS modality does not support single frame images.

Automatic Conversion of Screenshots

A Screenshot file is created each time the Print button is pressed on the **Galaxy™ System** Control Panel. This file is associated to the Frame in the Run that was displayed when the Print button was pressed. The DICOM Export dialog box provides a setting that will cause any Screenshots associated with a DICOM study to also be converted and transferred to the destination device (network or **Galaxy™ System** removable media). You may want to include Screenshots as a substitute for Bookmarks, which are not directly supported in the standard DICOM 3 specification for its IVUS or Ultrasound modalities.

The following item applies only to single Runs (not selected by Patient, Vessel, or Automated Transfer) that are copied to the DICOM folder or a disk drive icon:

Start Frame / End Frame

This setting allows you to specify the number of the first and last Frame in this Run to be converted to DICOM. This is best used with the Display Run button, so that you can see the Run on screen, and observe the Frame Counter values. When used in this manner, the button to the right of the Frame Entry Field can be clicked to automatically transfer the number of the currently displayed Frame into this field.

All incomplete DICOMNET transfers are maintained if the System enters Snooze Mode, or is shut down.

All instances of **Galaxy™ System** DICOM transfers (whether to local removable media, hard disk folders, or network) leave the original file unchanged. (The original Galaxy-formatted files are not altered, re-located, or deleted).

Quick Reference Procedure

If you are not familiar with the topics in the following Quick Reference procedure, please proceed to the detailed information in this chapter if necessary.

Automated DICOM Network Transfers

Locate the Patients/Vessels/Runs to be transferred in DiskView, then right-click on the labels of the items to transfer.

Right-click the DICOMNET folder, then select Set Auto Archival.

Optional – set a time delay to schedule the entire transfer process.

Click the Start Archival button. You can continue to select items and add them to an existing queue.

Update the Patient Database with the destination location.

To change the delay time after the Start Archival button has set the queue:

Right-click the DICOMNET folder, then select Set Auto Archival.

Click Cancel Archival in the Auto Archival Settings dialog box.

Set the new delay time, then click Start Archival.

Standard DICOM Network Transfers

Navigate to the Patient, Vessel, Run, or Screenshot to be transferred, then copy that item to the DICOMNET folder.

NOTE: When an individual Run (only) is copied, select desired parameters in the Export dialog box, then click Export.

If the Archive Destination dialog box is displayed, click listed destinations to select/deselect them, then click Send.

Update the Patient Database with the destination location.

DICOM Transfer to **Galaxy™** Disks

NOTE: MO media must be pre-formatted using the Microsoft/DICOM selection (FAT). CD-R, CD-RW and DVD+RW must be pre-formatted to CDFS unless DICOM files are copied to it – then they are auto-formatted.

Navigate to the Patient, Vessel, Run, or Screenshot to be transferred, the copy that item to the MO or CD/DVD drive icon.

PRECAUTION

If you attempt to copy files with inadequate storage space available, an MO disk formatted for DICOM transfers (FAT format) may become corrupted, resulting in the loss of all data on that surface (A or B) of the disk. To avoid this, always check for adequate storage space on an MO before initiating a DICOM copy operation.

NOTE: When an individual Run (only) is copied, select desired parameters in the Export dialog box, then click Export.

2. Update the Patient Database with the destination location.

Detailed Procedure

The following procedures explain how to convert Galaxy-formatted image files associated with Patients, Vessels, Runs, and Screenshots to the DICOM format, and then transfer that data to either a pre-configured DICOM Storage Server or **Galaxy™ System** removable media disk drive media. Please refer to the following section that corresponds to the operation you wish to perform. Each procedure covers both the process required to convert a copy of the Galaxy-formatted file to DICOM format, and then the transfer of that DICOM file to the desired destination. For simplicity, the entire operation will be referred to as a "DICOM Transfer".

NOTE: For ease of use and minimum impact on normal **Galaxy™ System** operations, for network transfers we recommend that you use the Automated DICOM Network Transfer method.

IMPORTANT

The conversion portion of all DICOM transfers suspends normal use of the system, which can take from a few minutes to several hours. This should be taken into consideration when initiating any DICOM transfer, whether to the DICOM Network, or to disk media. The Automated DICOM Network Transfer method allows a time delay to be set, which can help to minimize or eliminate this impact by scheduling the conversion and transfer process outside of normal usage hours.

IMPORTANT

If the Automated DICOM Network Transfer method is being used, and the processing has begun (i.e. not awaiting a selected time delay), the queue is closed and no additional items can be added. To add additional items, the Automated Transfer operation must be cancelled using the Cancel button in the DiskView window, and any remaining items will be removed from that queue. Next, rebuild the queue with the previous unprocessed items and the additions. It is usually advisable to schedule the queue for a time when normal system use is not likely to be required. This will allow additional items to be added (until the processing actually begins).

Automated DICOM Network Transfers

NOTE: Patient Last Name and ID number must be entered before the selected Galaxy-formatted item can be transferred to DICOM. DICOM transfers cannot be done during active imaging, playback, or during an Auto-Save.

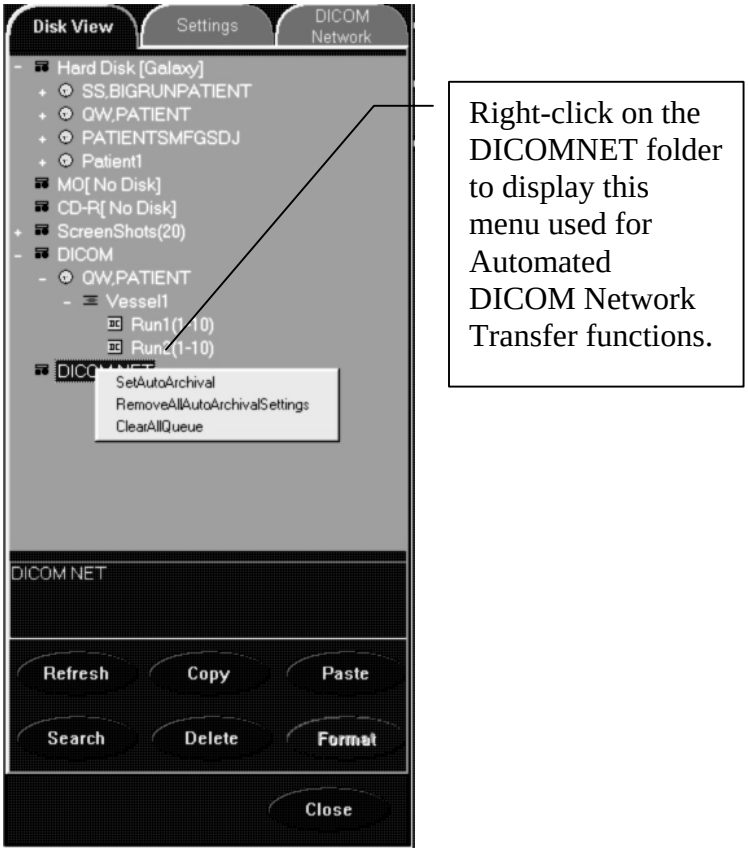


Figure 26 DiskView showing DICOMNET Pop-up Menu

Ensure that the **Galaxy™ System** is connected to the network. (Check the LAN (Local Area Network) connection on the Connector Panel).

Use the Trackball to select File from the Main Menu Bar.

Use the Trackball to explore the disk drives to locate the Galaxy-formatted Patients/Vessels/Runs to be transferred per normal DiskView methods.

NOTE: The item to be transferred must be on the Imaging Hard Disk. If it is on another **Galaxy™ System** disk drive, use standard DiskView operations to copy the file to the Imaging Hard Disk first, then select it as explained below.

Right-click on the labels of the items you wish to transfer. The label text will turn to green. Repeat this for each item to be transferred.

NOTE: The highest level selected in the Patient/Vessel hierarchy will automatically also select all related items (e.g., selecting a Patient will also select all related Vessels and Runs). You can then de-select any items that you do not want to transfer by right-clicking on those individual items (their green text label will return to normal when de-selected).

When the desired items are selected, right-click the DICOMNET folder to reveal the pop-up menu, then select Set Auto Archival.

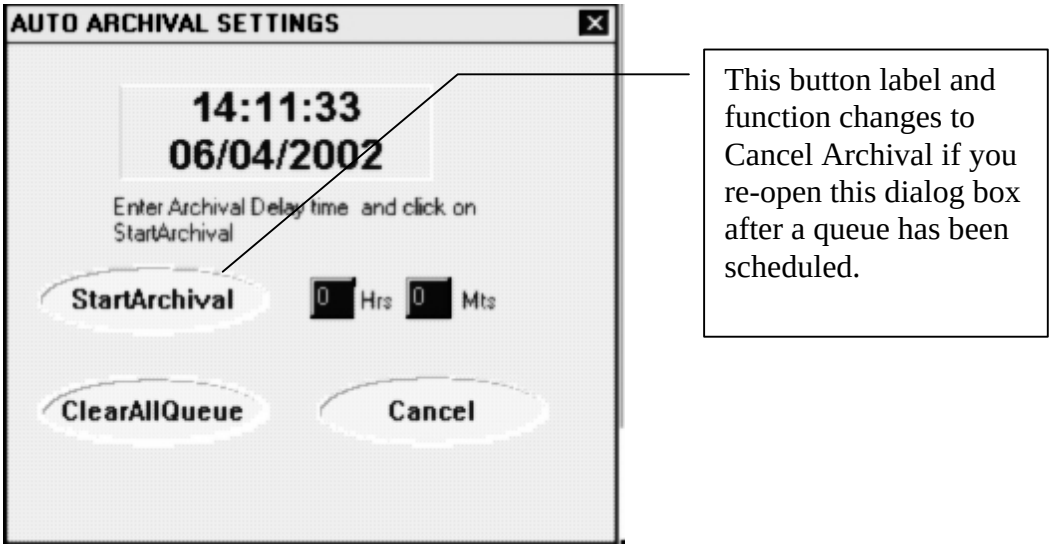

AUTO ARCHIVAL SETTINGS
14:11:33
06/04/2002
Enter Archival Delay time and click on StartArchival
StartArchival
0 Hrs
0 Mts
ClearAllQueue
Cancel
This button label and function changes to Cancel Archival if you re-open this dialog box after a queue has been scheduled.

Figure 27 Auto Archival Settings Dialog Box

Optional – if you wish to set a time delay to schedule the entire transfer process to start at a later time, use the Trackball to click in the Hrs (hours) field, then use the Keyboard to enter a value from 1 through 24. Repeat, if desired, for minutes (Mts.).

NOTE: The "Hrs" and "Mts." setting is a time delay from the current time of day displayed at the top of this dialog box.

HINT: It can be helpful to select a delay that will cause the processing to begin at a time when the System is not normally used.

Click the Start Archival button to start the time delay or the processing of the queue. The transfer process will begin immediately if no time delay was set; otherwise, it will start when scheduled.

You can continue to select items and add them to an existing queue in the same manner as explained above.

NOTE: The **Galaxy™ System** can be used normally during a scheduled delay time. If the system is currently being used for imaging or continuous image playback (only) when the delay time expires, it will be automatically rescheduled for thirty minutes later (and repeated as necessary until the system is not being used as stated).

HINT: The automatic rescheduling feature is only activated during active imaging or continuous playback. If the system is unused momentarily and the time delay expires during that idle time, queue execution will begin immediately, and the cancellation method must be used to regain normal use of the system.

To change the delay time after the Start Archival button has set the queue:

Right-click the DICOMNET folder to display the pop-up menu.

Select Set Auto Archival from the menu, which will display the Auto Archival Settings dialog box.

Click Cancel Archival in the Auto Archival Settings dialog box. The Cancel Archival button label will change to Start Archival.

Set the new delay time as explained earlier, then click the Start Archival button. The previously selected queue is now rescheduled for processing after the new delay time has elapsed.

PRECAUTION

Do not click the Cancel button in the DiskView window or the Clear All Queue button while items are in the queue; otherwise, all items that have not already been transferred to the DICOM network will be deleted from the queue, with no record maintained of items not transferred.

Each item that was pre-selected (by right-click) and then added to the automated queue (by the Start Archival button) is first converted to DICOM format and then individually automatically placed in the DICOMNET folder. The next item in the queue will not be acted upon until the previous item has been successfully transferred over the DICOM Network to the designated DICOM Storage Server(s). The **Galaxy™ System** will attempt to communicate with the default DICOM Storage Server(s) on the network. If this cannot be accomplished (e.g. the default Server may be busy or off-line) the image label will be changed to red. You can double-click the red label to view the status.

Standard DICOM Network Transfers

NOTE: Patient Last Name and ID number must be entered before the file can be transferred to DICOM.

NOTE: Only one Patient, Vessel, Run, or Patient Screenshot can be selected and transferred at a time using this method.

Ensure that the **Galaxy™ System** is connected to the network. (Check the LAN (Local Area Network) connection on the Connector Panel).

Use the Trackball to select File from the Main Menu Bar.

Use the Trackball to explore the disk drives to locate the Galaxy-formatted Patient/Vessel/Run to be transferred.

NOTE: Execution of the next steps will immediately suspend normal use of the System while the Galaxy-formatted item is being converted to the DICOM format. Only the Cancel button in the DiskView window will be enabled during this process. You can use it to cancel the process and restore normal system operation if necessary. If Cancel is used, any items that were not converted to DICOM are not held in a queue for future conversion. If you must cancel the operation, you can use DiskView to examine which items were successfully transferred, and repeat the above steps if necessary at a later time to reselect any items that were not converted.

Use the Trackball to navigate to the Patient, Vessel, Run, or Screenshot (in the Screenshots folder) to be transferred.

Click to select that item, then Copy and Paste or Drag and Drop that item to the DICOMNET folder.

NOTE: If a Patient, Vessel, or Run is copied to the DICOMNET folder, the default settings for image compression, DICOM modality, and Screenshot inclusion are used. In such cases, skip to step 13. For individual Runs only, the following alternate method can be used, which allows you to individually set the selections for compression, DICOM Modality, Screenshot inclusion, and optionally select a subset of the Frames in the Run for transfer.

NOTE: Non-IVUS Screenshot files (e.g., Pre-Post screen, Report screen, etc.) cannot be copied to the DICOMNET folder. (Ignore the "Copy finished successfully" message).

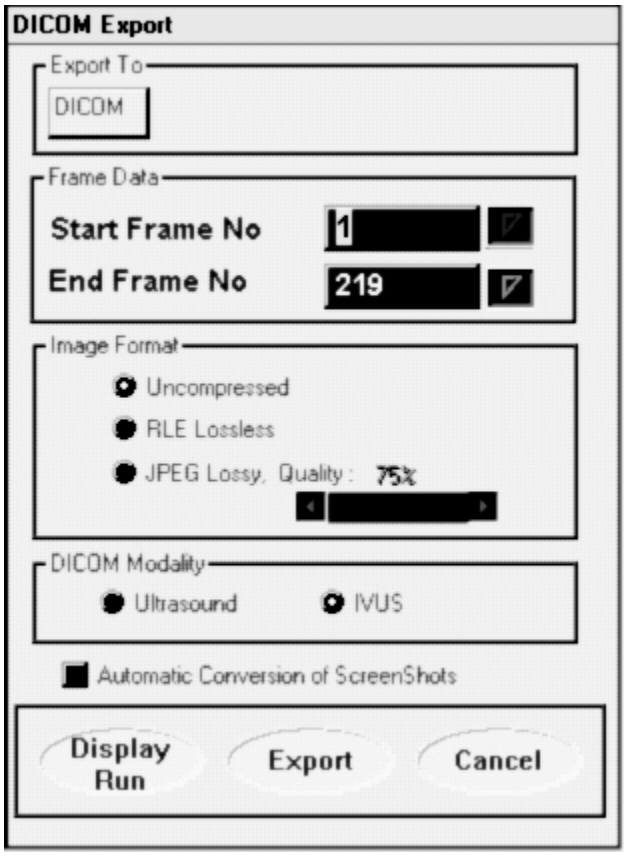


Figure 28 DICOM Export Dialog Box

When an individual Run is copied to the DICOM (not DICOMNET) folder, the DICOM Export dialog box is automatically displayed.

Optional - **Frame Range** - if you wish to transfer less than the entire Run, click the Display Run button. The selected Run is shown in the image area of the screen.

Use normal **Galaxy™ System** controls to locate the beginning of the section of this Run that you want to transfer to DICOM, then click the button to the right of the Start Frame No. field. The currently displayed Frame's number will be automatically entered.

Repeat this for the last Frame you want to include in the transfer.

HINT: During this process you may also want to press the Print key to create a Screenshot file of each Bookmarked Frame, since the transfer process does not include Bookmarks.

Optional – **Image Compression** – if you wish to change the compression setting from its current (default) state, use the Trackball to select the type of image compression (and the level, for JPEG).

WARNING

JPEG compression may degrade both the spatial and grayscale quality of the stored image, even at the highest quality (100%) setting. This could impact the diagnostic quality of the images.

PRECAUTION

Ensure that the institution's DICOM Viewing Stations are compatible with JPEG and RLE Lossless compression before utilizing those settings.

Optional – **DICOM Modality** - if you wish to change the DICOM Modality setting from its current (default) state, use the Trackball to select the DICOM Modality – either ultrasound or IVUS. (IVUS is the preferred setting if the Viewing Stations support that modality).

Optional – **Screenshot inclusion** - if you wish to change the Screenshot inclusion setting from its current (default) state, use the Trackball to set or clear the check mark for Automatic Conversion of Screenshots (set the check mark if you want any Screenshots that are associated with this Run to be included with the DICOM transfer).

Use the Trackball to click Export when all the desired settings have been made.

Use the Trackball to Copy and Paste the item from the DICOM folder to the DICOMNET folder.

If the **Galaxy™ System** is configured to display the DICOM Archive Destination dialog box, it will now be shown (otherwise the transfer will be sent to the **Galaxy™ System** default Storage Server(s)). To select (highlight) or de-select a Storage Server, use the Trackball to click each desired item listed. When selection is complete, click the Send button at the lower right of this dialog box. The conversion and transfer begins immediately.

Normal **Galaxy™ System** operation is suspended while the item is being converted to the DICOM format, but restored while the file is being transferred over the network.

To view the item's status, click the DICOMNET folder. The color of the item's Run (image) label text indicates its status:

Green - Patient or Vessel-level items whose related Runs (images) are awaiting transfer or being transferred
Blue – being transferred or awaiting transfer
Red – transfer failed

Where items are shown in red, you can double-click on its label to see the error message in the Status Area of the DiskView Window.

Once the item has been successfully transferred to the DICOM Network Server, its label will be automatically deleted from the DICOMNET folder.

Figure 29 DICOM Storage Destinations Dialog Box

Update the Database

To update the Patient Database with this new storage location, do the following:

NOTE: If the patient has a Run currently displayed on screen, skip to step 16 below.

Use the Trackball to select File from the Main Menu Bar, then explore the disk drives to locate the patient on any listed disk drive (containing Galaxy-formatted media).

Click on the + icon next to the patient name label to list Runs for that patient, then double-click any Run to display it on screen (this will load this patient's data into the Patient Window when it is next displayed)

Press the Patient Button on the Control Panel to display this patient's data.

If the data in the Disk # or Tape # column needs to be updated or entered, use the Trackball to click in the Disk or Tape field, then use the Keyboard to enter the transferred file's network location.

Click Enter to save the displayed values in the database.

NOTE: The "Tape" entry can be alternately be used to indicate a DICOM Network Server location (e.g., DS-101 for DICOM Storage Server number 101). Up to eight characters are available. This approach can be used if images are archived in both the Galaxy format and on a DICOM Network Storage Server, and videocassette (i.e., Tape) is not used being for archival purposes.

DICOM Transfer to **Galaxy™** Disks

Formatting New Media

MO media that has not been previously used for storage must be formatted first. MO, CD-R or DVD+RW media that has been formatted to store Galaxy-formatted images cannot be used to store DICOM files or Screenshot files. CD/DVD media can be formatted automatically with the format of the files being written to that disk; however, you may prefer to pre-format it as explained below. This then gives the advantage of providing the same Copy and Paste storage methods as used with the other drives. If you do not wish to pre-format the disks, or if the media being used has already been formatted, skip to "DICOM Transfers to **Galaxy™ System** Removable Media" below.

Formatting cannot be done when imaging or playback is active. MO disks have a write-protect setting on their housing, and cannot be formatted (or written to) when write protected.

Insert the desired new media into the destination drive (MO, CD-R, CD-RW, or DVD+RW).

NOTE: MO disks have two storage surfaces. The MO Drive can only access one side at a time; therefore, each surface must be formatted separately. The MO Disk must be manually removed, flipped side-to-side, and then re-inserted. Each side can be formatted with a different format type if desired.

Use the Trackball to select the File Menu, then select the DiskView Window.

Use the Trackball to double-click the icon for the appropriate removable media drive.

Select the Settings Window in the File Menu, then select the Microsoft/DICOM compatible format (for MO or CD/DVD disks. Disks formatted for DICOM will be subsequently shown as "FAT" for MO disks, and "CDFS" for CD/DVD disks).

Use the Trackball to select the Disk Drive containing the media to be formatted, then click the Format Button.

PRECAUTION

Do not format media that contains data that you want to retain – formatting will irretrievably remove any existing data. Transferring data to a CD-R will cause that CD-R to be write-protected from future storage.

NOTE: Occasionally, formatting an MO disk in FAT format results in a list of invalid files after Refresh is clicked in DiskView. If this occurs, there has been an error in the formatting process. Re-format the MO disk. If the problem recurs, the MO disk may be bad and should not be used.

DICOM Transfers to Galaxy™ Removable Media

NOTE: Patient Last Name and ID number must be entered before the item can be transferred to DICOM. DICOM transfers cannot be done during active imaging or playback.

NOTE: Only one Patient, Vessel, Run, or Patient Screenshot can be selected and transferred at a time.

Insert the desired destination media into the destination drive (MO, CD-R, CD-RW, DVD+RW).

HINT: If the patient to be transferred has previously transferred records, it is helpful to use that same media if storage space is available. Images cannot be added to a CD-R that has been finalized earlier; however, their previously transferred images can be copied to a new CD-R.

NOTE: If you are transferring to a CD-R, that technology limits writes to once only per CD-R. If you desire to transfer multiple items to a CD-R, you should have those files determined and located before beginning. Do not respond "Yes" to "Do you want to finalize the CD?" until all data to be written to that CD-R disk has been pre-selected. Additional items cannot be written to a CD-R that has been

"finalized". CD-R's being written cannot be removed from the CD-R Drive until the finalization step has been executed.

You may also want to check your institution's guidelines regarding archiving medical images on CD/DVD media.

Use the Trackball to select the File Menu, then select the DiskView Window.

Use the Trackball to select the icon for the disk drive where the desired items are located, then navigate to the Patient, Vessel, Run, or Screenshot to be transferred.

NOTE: Execution of the next step will suspend normal use of the **Galaxy™ System** while the Galaxy-formatted item is being converted to the DICOM format. Only the Cancel button in the DiskView window will be enabled during this process. You can use it to cancel the process and restore normal system operation if necessary. Items that were not converted to DICOM are not held in a queue for future conversion in such cases. You can use DiskView to examine which items were converted and copied to the destination disk, and repeat the above steps if necessary to reselect the files that were not converted at a later time.

1. Click to select that item, then Copy and Paste or Drag and Drop that item to the desired destination.

NOTE: Files cannot be copied to a DICOM (FAT)-formatted MO by dropping them on the MO's expanded tree. Copy the file directly to the folder representing the MO drive (which is the best method to use for all copy operations), not to the tree structure.

PRECAUTION

If you attempt to copy files with inadequate storage space available, an MO disk formatted for DICOM transfers (FAT format) may become corrupted, resulting in the loss of all data on that surface (A or B) of the disk. To avoid this, always check for adequate storage space on an MO before initiating a DICOM copy operation

NOTE: An alternative method for CD-R storage of DICOM files is to first copy them to the DICOM folder, then to copy them to the CD-R Drive. This eliminates pre-formatting the CD-R disk. Using this method, the System automatically selects the correct format method based on the type of files being stored on the disk.

PRECAUTION

Copying a patient that has not yet been identified to a CD, results in the CD being automatically formatted using the Galaxy format.

NOTE: If a Patient or Vessel is copied to a disk drive icon, the default settings for image compression, DICOM modality, and Screenshot inclusion are used. For individual Runs only, the following method can be used, which allows you to individually set the selections for compression, DICOM Modality, Screenshot inclusion, and optionally select a subset of the Frames in the Run for transfer.

When an individual Run is copied to DICOM formatted removable media, the DICOM Export dialog box is automatically displayed.

Optional - **Frame Range** - if you wish to transfer less than the entire Run, click the Display Run button. The selected Run is shown in the image area of the screen.

Use normal **Galaxy™ System** controls to locate the beginning of the section of this Run that you want to transfer to DICOM, then click the button to the right of the Start Frame No. (number) field. The currently displayed Frame's number will be automatically entered.

Repeat this for the last Frame you want to include in the transfer.

HINT: During this process you may also want to press the Print key to create a Screenshot file of each Bookmarked Frame, since the transfer process does not include Bookmarks.

Optional – **Image Compression** – if you wish to change the compression setting from its current (default) state, use the Trackball to select the type of image compression (and the level, for JPEG).

WARNING

JPEG compression may degrade both the spatial and grayscale quality of the stored image, even at the highest quality (100%) setting. This could impact the diagnostic quality of the images.

PRECAUTION

Ensure that the institution's DICOM Viewing Stations are compatible with JPEG and RLE Lossless compression before utilizing those settings.

Optional – **DICOM Modality** - if you wish to change the DICOM Modality setting from its current (default) state, use the Trackball to select the DICOM Modality – either

ultrasound or IVUS. (IVUS is the preferred setting if the Viewing Stations support that modality).

Optional – **Screenshot inclusion** - if you wish to change the Screenshot inclusion setting from its current (default) state, use the Trackball to set or clear the check mark for Automatic Conversion of Screenshots (set the check mark if you want any Screenshots that are associated with this Run to be included with the DICOM transfer).

Use the Trackball to click Export when all the desired settings have been made.

Use the Trackball to Copy and Paste the item from the DICOM folder to the desired disk drive icon).

Update the Database

To update the Patient Database with this new storage location, do the following:

Use the Trackball to select File from the Main Menu Bar, then explore the disk drives to locate the patient on any listed disk drive (containing Galaxy-formatted media).

Click on the + icon next to the patient name label to list Runs for that patient, then double-click any Run to display it on screen (this will load this patient's data into the Patient Window when it is next displayed).

Press the Patient Button on the Control Panel to display this patient's data.

If the data in the Disk # or Tape # column needs to be updated or entered, use the Trackball to click in the Disk or Tape field, then use the Keyboard to enter the transferred file's network location.

Click Enter to save the displayed values in the database.

NOTE: The Tape column can also be used to indicate a DICOM Network Server location (e.g., DS-101 for DICOM Storage Server number 101). Up to eight characters are available.

Chapter 7 Overhead Monitor Switchbox (OMS)

This Chapter provides technical information for understanding the operation and installation requirements for integrating the **Galaxy™ System** IVUS Imaging Overhead Monitor Switchbox (OMS) with Cath Lab x-ray systems. This chapter contains:

- description of OMS system operation
- overview of the installation process
- wiring diagrams and schematics
- frequently asked questions

Note: All Galaxy™ instruments are OMS enabled to work with the OMS.

Galaxy™2 instruments may not be OMS enabled where a field service visit is required for activation. Please forward all inquiries regarding OMS to: ivus.techsupport@bsci.com

Galaxy™ System and the Overhead Monitor Switchbox

The **Galaxy™ System** has been designed to simplify the use of IVUS in the cath lab. The **Galaxy™ System** can provide a High-Resolution IVUS Video Output compatible with most cath lab roadmap video monitors.

Two reasons for utilizing this **Galaxy™ System** feature:

1) This allows more convenient viewing of the **Galaxy™ System** console so that the physician can see the display.

2) The OMS also allows the **Galaxy™ System** to store and display x-ray and IVUS images together, which may help the physician when reviewing a case. The **Galaxy™ System** uses a single Lemo® cable to provide a rapid, convenient connection to the x-ray video monitors. In addition, The **Galaxy™ System** will store and automatically recall the video parameters (brightness, contrast, position, aspect ratio) associated with the roadmap monitor in each cath lab.

To help in meeting this objective, Boston Scientific has developed the Overhead Monitor Switchbox (OMS). The OMS is a 6 5/8" x 4 5/8" x 4 1/8" metal box, and weighs approximately 32 oz. The OMS will be permanently installed in each cath lab that will utilize the integrated video features of the **Galaxy™ System**. The OMS is connected between the x-ray rack and the cath lab overhead monitors. Installation of the OMS is a

technical procedure and must be performed by those who have been consulted by Boston Scientific or a BSC Field Service Engineer.

Figure 30 The OMS is connected to the "live" fluoro and reference roadmap monitors and mounted on the monitor yoke assembly.

Overhead Monitor Switch Box - Basic Functionality

The **Galaxy™ System** gains access to the roadmap and fluoroscopy x-ray video via the OMS. The video between the x-ray rack and the x-ray monitor is routed through the OMS. Installed properly, in compliance with the OMS procedure, the OMS will not affect the quality of the x-ray video signal.

The OMS is connected to the x-ray system by way of standard video cables. The **Galaxy™ System** is connected to the OMS using a specialized cable with a Lemo® connector, available from Boston Scientific.

The fluoroscopy video is 'looped through' the OMS and is always present on the x-ray monitor. Inside the OMS, the live fluoroscopy video is 'tapped' by the **Galaxy™ System** to identify the x-ray video format being used and to provide fluoroscopy images for use by the **Galaxy™ System**.

The roadmap video signal also passes through a closed circuit inside the OMS via a relay switch. The **Galaxy™ System** operator is able to 'toggle' the roadmap monitor's display by selecting OVERHEAD on **Galaxy™ System**'s top panel. When IVUS is selected to be displayed on the Road-map monitor, the relay switch 'opens' and cuts off the roadmap video displaying the IVUS image instead. When the **Galaxy™ System** is turned off, or the Lemo® cable is disconnected, the Road-map video relay is closed inside the OMS providing normal viewing of the Road-map video image on the x-ray monitor.

The OMS is a 'passive' device deriving its power from the **Galaxy™ System** (+/-5 volts) through the Lemo® cable. OMS video connections are completely isolated from the **Galaxy™ System** ground.

Installation Options for the OMS

- The Overhead Switchbox can access the x-ray video signal at two locations in the x-ray system; either at the x-ray monitors or inside the x-ray card rack (certain labs may offer additional options).
- Mounting the OMS at the x-ray monitors and connecting to the x-ray video at the monitors is the simplest and most cost-effective installation. The installation process should take approximately 1 ½ hours.
- The OMS may be installed inside the x-ray system's Card Rack. This installation option is more expensive and labor intensive. Labor estimate for this option is 4 to 8 hours. This option requires the use of a long Lemo® cable (routed through the floor or ceiling) between a junction box (located on a wall or underneath the x-ray table) and the OMS inside the rack.

Note: Siemens manufactures an x-ray system that displays the live fluoroscopy and Road-map video images on a single monitor. The live fluoroscopy can never be interrupted and so this monitor is not capable of displaying the IVUS image. Another Hi-Resolution monitor or flat screen display (not provided) would be required to display the IVUS image.

Materials Required to Install the OMS

The Overhead Monitor Switchbox is a unique, proprietary device and is only available from Boston Scientific.

Typically, one OMS is installed per x-ray room. The Lemo® Cable required to connect the **Galaxy™ System** to the OMS is also unique and only available from Boston Scientific. Typically, the **Galaxy™ System** will utilize one 15' Lemo® Cable. This cable will remain attached to the **Galaxy™ System** unit as it moves from room to room.

These specialized multi-conductor Lemo® cables are available in lengths of 15, 30, and 60 feet, depending on the installation method. The longer lengths are used in x-ray card rack installations. Any combination of these Lemo® cables not exceeding 75 feet can be used. The junction box is used to connect cables of various lengths together.

75Ω BNC-BNC video cables are required to connect the OMS to the x-ray system and are provided by Boston Scientific. They have been quality tested by Boston

Scientific. Use of these cables will not degrade the quality of the x-ray video provided that the length of each video cable used is no longer than 5 feet per cable.

Depending on the type of installation, other miscellaneous supplies for mounting the OMS and dressing the cables may be required. These will be supplied by Boston Scientific.

Galaxy™ System OMS Frequently Asked Questions

1. We only wish to view the IVUS image on our overhead road-map monitor and are not interested in viewing the live fluoroscopy image on the **Galaxy™ System**. Do we still need to connect the **Galaxy™ System** and the Overhead Monitor Switchbox to the x-ray system?

   Answer: Yes. In order for the **Galaxy™ System** to determine the correct x-ray video format unique to your x-ray system, it must have x-ray video connected to the 'fluoro' input on the OMS.

2. We are already connecting the output of the ClearView® Ultra™ System to our x-ray system. Can we continue to do this with the **Galaxy™ System**?

   Answer: Yes.

   - Installation of the OMS is not necessarily required to view **Galaxy™ System i**mages on an external monitor. The **Galaxy™ System** provides both a BNC and S-Video output connector for the standard 525 line NTSC or 625 line PAL video signal. See Figure 15. However, a significant improvement in video quality will be realized if the Hi-Resolution Video output signal from the **Galaxy™ System** and the OMS is utilized. Also, when using the standard video output, the video parameters of the IVUS image cannot be controlled (brightness, contrast, position, and aspect ratio) from the **Galaxy™ System** software. The roadmap monitor is calibrated by your x-ray service engineer to make the roadmap image look optimal. When the IVUS image is placed on the same monitor using the **Galaxy™ System's** standard video output the image may look sub-optimal.

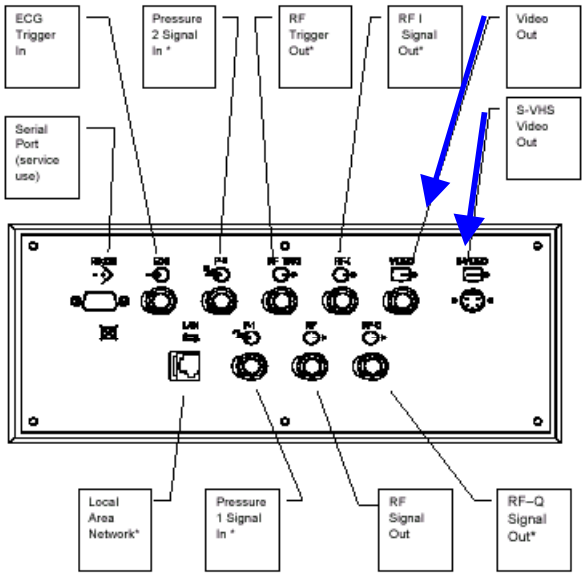


Figure 31 **Galaxy™** input/output connectors located at the back of **Galaxy™**

- Additionally, **Galaxy™2** may offer, either through a production model or an upgrade, a standard SVGA computer output connector. This provides excellent video quality through a dedicated computer monitor display, such as an LCD display.

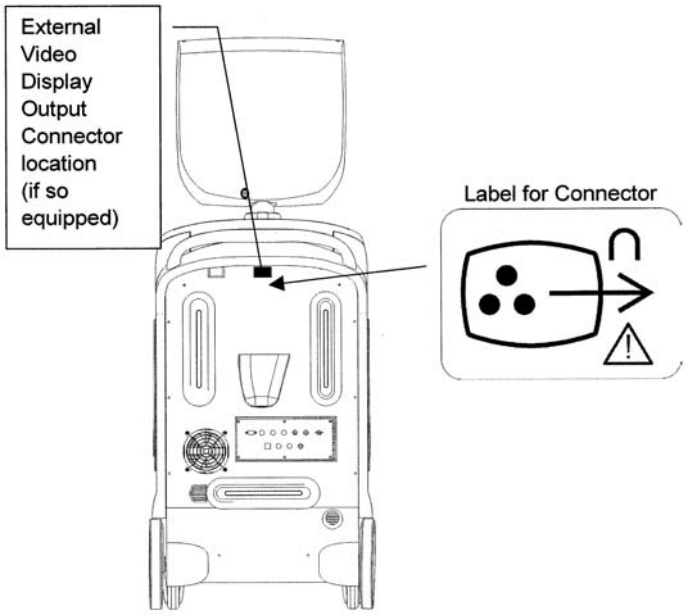


Figure 32 **Galaxy™2** SVGA Connector Location

3. How is the IVUS image adjusted to improve the image on our roadmap monitor when we utilize the OMS?

   Answer: Once the OMS is installed there are necessary adjustments using the **Galaxy™ System** software to make all the video displays optimal; e.g. brightness, contrast, position, aspect ratio. These adjustments are embedded in a special service menu in the **Galaxy™ System** software and can only be accessed (password required) by Boston Scientific direction.

4. Can our x-ray service engineer install the OMS?

   Answer: Provided your x-ray service engineer has been consulted by Boston Scientific, they may install the OMS hardware. Boston Scientific encourages the participation of your x-ray Service Personnel in this process and requires participation for OMS installations inside the card rack.

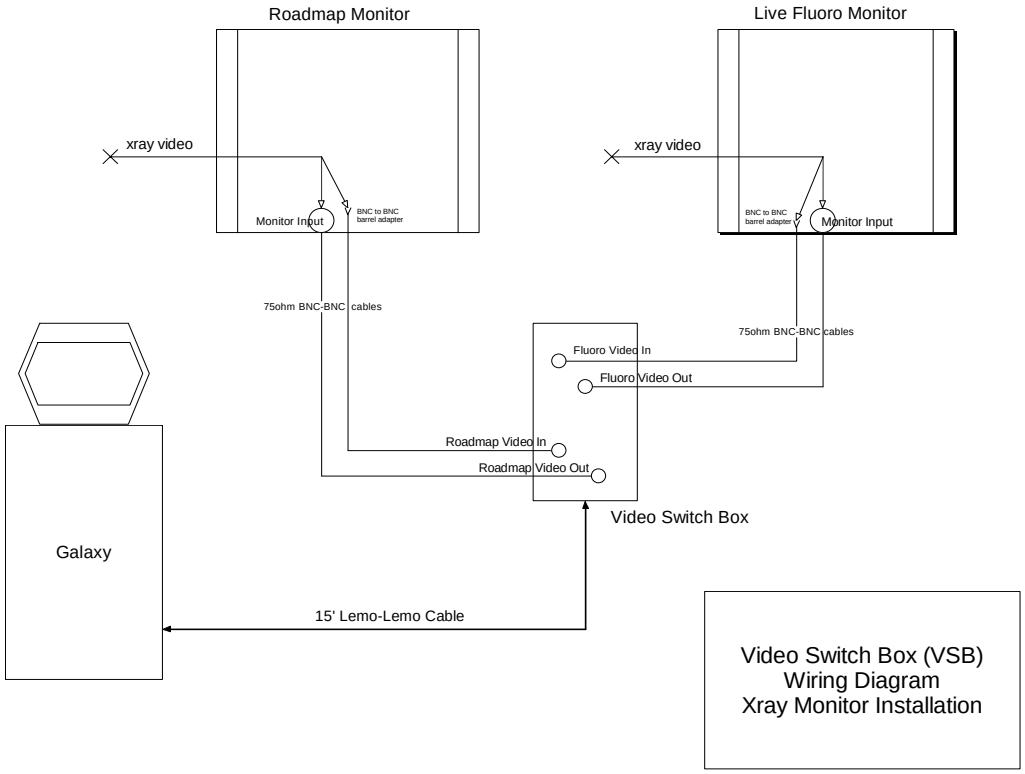
5. Are the video connections to the OMS isolated?

   Answer: Yes. OMS video connections to the x-ray system are isolated from the **Galaxy™ System** ground and the video connections will have no effect on the x-ray system's isolation.

6. What 'exactly' will your IVUS Field Service Engineer be doing to our x-ray system in order to connect the OMS?

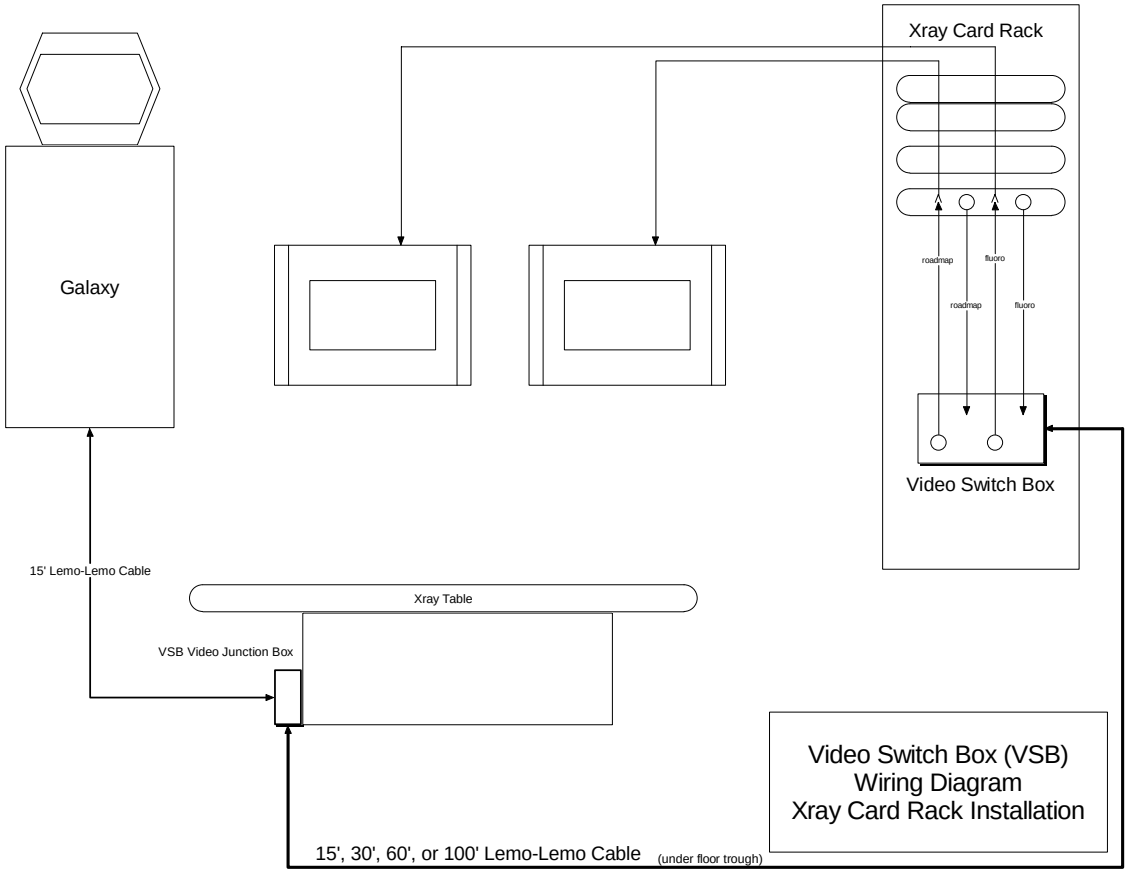
   Answer: That depends on the type of OMS installation.

Installation at the x-ray monitor (Diagram 1)



Here, wiring and mounting the OMS is very straightforward. The x-ray video cable attached to the x-ray monitor is disconnected. Typically this is a BNC type connector and is easily removed. Sometimes this requires removal of the back of the x-ray monitor. A BNC-BNC to barrel adapter is attached to the x-ray cable. The FSE then installs a 75Ω BNC-BNC cable (less than 5' in length) to the other end of the barrel adapter and connects this cable to the OMS x-ray "video in." Another 75Ω BNC-BNC cable connects to the OMS x-ray "video out" and is routed back to the x-ray monitor. This procedure is performed twice; once at the live fluoroscopy monitor and once at the roadmap monitor. The OMS is physically mounted nearby in a convenient unobtrusive location.

Installation in the x-ray card rack (Diagram 2)



Participation by x-ray Service Personnel is required. Boston Scientific Field Service Engineers will not open the x-ray card rack or make any connections inside the card rack other than to the OMS itself. Boston Scientific Field Service Engineers will advise x-ray Service Personnel of the correct wiring procedure for connecting the OMS inside the card rack and may participate in the routing of cables through the floor or ceiling and installation of the video junction box. The video connected to the OMS in the card rack is accessed in the same manner as when connected at the monitor. However, instead of disconnecting the x-ray video cable at the monitor, the same video source is identified inside the card rack and accessed there.

7. We have a variety of x-ray systems in our Cath Lab. Will the **Galaxy™ System** interface with all the different manufacturers?

Answer: The **Galaxy™ System** is designed to provide a High-Resolution Video Output compatible with most x-ray video formats. The supported x-ray formats are:

- RS-170 525/60, PAL 625/50
- Siemens 1023/60, 1249/50, 1023/120
- GE 1023/60, 1249/50
- Phillips 1049/60, 1066/76
- Shimadzu 1125/60

The **Galaxy™ System** may be compatible with x-ray systems produced by other manufacturers, provided that the x-ray video format matches (or is very close to) one of the supported formats.

8. How will the **Galaxy™ System** recognize various manufacturer's x-ray systems when it is moved from one cath lab room to another?

Answer: Inside the OMS there is a preset switch that identifies the room in which the OMS is installed. There are up to seven different room identification settings available. This feature allows the **Galaxy™ System** software to recall the saved configuration settings for a particular room.

9. Can the **Galaxy™ System** or the OMS damage our x-ray system?

Answer: No.

- The video signal output of the **Galaxy™ System** is similar to the video signal of the x-ray system.
- In the case of a component failure inside the OMS, there could potentially be a temporary loss fluoroscopy video. The likelihood of this occurring is extremely remote. Following three years (as of this writing) of OMS usage, no such problem has been reported. Should such an event ever occur, fluoroscopy video can be immediately restored to the x-ray monitor by 'simply' unplugging the Lemo® cable connector from the OMS.

Provided the proper **Galaxy™ System** and OMS installation procedures are followed, Boston Scientific knows of no other scenario where the OMS installation could have any effect on the x-ray system's performance.

10. Can we put the IVUS image on a live Fluoro monitor? For example, we have a bi-plane Siemens x-ray system with only two monitors that mix both live fluoro and reference video on each monitor. We do not use the bi-plane very much and would like to put IVUS on one of those monitors.

Answer: No. Not under any circumstance may a live fluoro monitor be interrupted. When the physician steps on the floor pedal, the live fluoro image must appear at all times on the x-ray monitor. IVUS may only be displayed on a non-essential monitor; e.g., roadmap, reference, dedicated IVUS. Although Fluoro is connected to the OMS, the video signal is never interrupted as shown in the OMS schematic below.

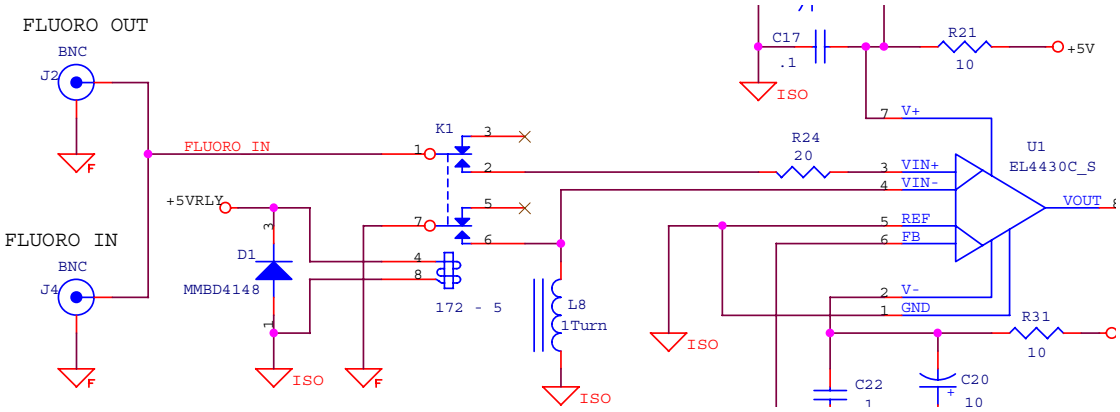


Figure 33 OMS (partial) schematic

11. We do not have the OMS installed now. How may we acquire this option?

Answer: Contact your Boston Scientific Sales Representative.

Note: Boston Scientific requires that a hold-harmless agreement be signed prior to OMS installation and integration with an x-ray system. Your sales person can provide more details regarding this.

Chapter 8 Galaxy™ System Parts Replacement

Overview

This chapter provides instruction for removing and replacing the internal subassembly components of **Galaxy™** and **Galaxy™²**. These procedures are intended for field service engineers and biomedical equipment technicians.

Procedures

Note:

- No specialized tools are required to remove and replace internal components unless noted.
- To replace a part once removed, reverse the part removal procedure.
- Removed tie wraps must be replaced as found.
- Use grounding wrist straps whenever dealing with static sensitive components.
- Locate all reference drawings or pictures in **Chapter 10: Diagrams**.

Removal of Galaxy™ System covers

Galaxy™ reference drawing 51237-000
Galaxy™² reference drawing 50374-001

Front cover removal

1. Remove the three Phillips screws at the top of the front cover located underneath the CD ROM drive and the keyboard.
2. Pull the front cover away from the system (grab from bottom and pull out).

Back cover removal

1. Remove the twelve Phillips screws attaching the back cover.
2. Remove the MDU holder by pressing up in the center of the bottom of the holder and pulling out from the top.
3. Remove the four nuts behind the MDU holder.
4. Pull the back cover away from the system.

Top Control Panel assembly removal

1. Remove the front cover.
2. Gently lift the far corners of the Control Panel near the back. It may be helpful to lift up one corner first with a flat blade screwdriver to get it started (while being careful not to scratch the paint). The Control Panel will pull completely off from the system but will still be attached by cables.
3. Disconnect the three cable connectors and the ground wire and set the top panel aside.

Side covers removal

1. Remove the front cover, top Control Panel and back cover.
2. Remove the Phillips screw (from inside) near the top center of each side covered (drawing 50374-001, Detail A). Remove the Phillips screw near the bottom center of each side cover.
3. Pull each side cover away from the system

Back Panel removal (drawing 51236-000)

1. Remove the front cover, top Control Panel, back cover and side covers.
2. Remove the ten screws (five on each side) to drop down the hinged back panel.

CAUTION

Caution: There is no lanyard in place to protect the panel from 'free-falling.' Exercise caution when removing or lowering the Back Panel to prevent injury or damage to system components.

Note: When reinstalling the back cover it may be helpful to slide out the PC a little towards the front.

On/Off switch

1. Remove the back cover.
2. Remove tie-wraps as needed to gain access.
3. Pry the switch out (not necessary to remove the bracket) and remove the wires.

Note: Correct switch orientation will have it wired with the white wire center top, black wire top left, red wire center bottom, green wire right bottom (facing the back of the system).

Internal VME Lemo® Cable

1. Remove all covers.
2. Drop down the back panel.
3. On the inside bracket of the Lemo® connector (where the motor drive unit plugs in), remove the four nuts. Use an 11/32" nut driver with a long shaft 6" to 12" (a flex extension maybe best) and approach from the front of the system, underneath the monitor.
4. Disconnect the other end of the cable at the back of the VME card cage and remove.

Video Scan Converter

1. Remove all covers.
2. Drop down the back panel.
3. Disconnect the cables going to the scan converter.
4. There are two brackets on each side holding the scan converter to the back panel assembly. Remove the four screws from each bracket and the scan converter may be removed. Depending on the **Galaxy™ System** version, it may be necessary to remove the eight 5/16" nuts to enable access to these screws.

Isolation PCA

1. Remove all covers.
2. Drop down the back panel.
3. Remove the 5/16" nuts holding Isolation PCA cover.
4. Remove tie-wraps as needed to gain access.
5. Remove the four BNC connector cables attached to the Isolation PCA.
6. Remove the gray ribbon cable which connects to the BNC connectors mounted on the back panel.
7. Remove the two video cables J18/J19, RF Trig, three RS232 connectors, J21/J22 power cables and J22 video to the back plane.

8. Remove the white cover plate on the back of the system by removing all the nuts holding the BNC connectors. Remove the four screws holding the PCA in place. The Isolation PCA may now be removed.

Note: Make sure the four BNC cables are not caught under the cover when you reinstall it.

Merlin VIF PCA

1. Remove all covers.
2. Remove the Merlin assembly cover; 4 screws.
3. Disconnect all cables and connectors attached to the PCA.
4. There are eight screws holding the large back metal plate that the Merlin assembly is mounted to. Remove the eight screws and pull the back plate with Merlin attached away from the system.
5. Remove the Merlin PCA board from its mount to the back plate by removing the five 11/32" nuts on the back of the plate.
6. Remove the written serial number of the swapped out PCA from the Merlin cover with a alcohol wipe. Write in the serial number from the new PCA with a Sharpie® pen.

VME Power Supply

1. Remove all covers.
2. Drop down the back panel.
3. Disconnect all cables and connectors going to the supply.
4. Remove the front fan plate assembly (four screws).
5. Remove the four screws holding the supply in place (two in front, two in back).
6. Lift the VME power supply out through the side of the system. Tilt the top out first. You may have to use gentle force or a thin pry bar to remove and install the supply.

Low Voltage Power Supply Assembly

Note: Contains 3 built-in supplies – gray colored assembly

1. Remove all covers.
2. Drop down the back panel.
3. Disconnect all cables and connectors going to the supply.
4. Remove the front fan plate assembly (four screws).
5. Remove two screws in the front and two screws in the back.

6. Loosen the eight 'spring loaded' screws on the under side of the gray colored power supply assembly. An 8" plus Philips will be required.
7. Remove tie-wraps as needed to gain access.
8. Make sure area is clear of cables (may help to slide out the PC a little) and slide the power supply out the back of the system.

Un-interruptable Power Supply (UPS)

1. Remove all covers.
2. Drop down the back panel.
3. At the back of the UPS, disconnect the serial cable, unplug A/C attachment, remove the UPS A/C input wires from J4 at the A/C Distribution PCA.
4. Remove the front fan plate assembly (four screws).
5. Using a 9/64" Allen hex-driver (8" shaft length required), remove the nine screws holding the front bezel of the UPS.
6. Slide the UPS out the front of the system. Push from the back. Do not pull on the front of the UPS.
7. Prepare the new UPS for installation.
    a. Remove the front panel (hinged, pull from top) and connect the battery. The UPS should never be shipped with the battery connected and will arrive in this manner.

CAUTION

Caution: Failure to connect the battery prior to usage may result in a catastrophic failure of the UPS which may include fire.

    b. Plug the UPS into a wall outlet. On the back of the UPS next to the power cord, there's a 'sensitivity' switch. Next to that, there is a green LED. The 'sensitivity' switch has three levels of brightness (bright, dim, not lit). Push the switch and set UPS sensitivity to dim – medium sensitivity.
    c. Unplug the UPS. Cut the UPS A/C power cord to the exact length of the UPS A/C power cord that was removed. Strip wires similarly.
    d. Remove the rubber feet from the bottom of the UPS.

Note: The UPS that was removed may have four bottom screws missing which hold the UPS case to the UPS chassis. In any event, those four screws should be installed (left in place) on the UPS being installed back into the **Galaxy™ System**. Newer

UPS's being removed from the **Galaxy™ System** may have lower profile screws installed, which can make installation of the UPS easier. They may be swapped, although not required.

8. Slide the UPS into the **Galaxy™ System**. Install the front holding bezel. Reinstall the fan plate.
9. Attach the serial cable, A/C plug, and A/C wires as they were removed. The UPS A/C input should be connected as follows to J4 at the A/C Distribution PCA: [J4, 3 = black] [J4, 4 = white] [J4, 6 = green]. Screw in wires securely at J4.
10. Plug the **Galaxy™ System** in for at least an hour prior to use.
11. Verify UPS functionality by testing the snooze feature. (Snooze, unplug the **Galaxy™ System**, verify PC & display power maintained.)

UPS Controller PCA

Note: The UPS Controller PCA is different between **Galaxy™** and **Galaxy™²**.
Verify correct part number and revision prior to replacing.

1. Remove the front and side cover on the right, facing the **Galaxy™ System**.
2. Disconnect all plugs (4X) and cables (2X) going to the UPS Controller PCA.
3. Remove 4 6/32" KEPS nuts located at each corner of the UPS Controller PCA.
4. Remove UPS Controller PCA .

Trackball

1. Remove the front cover and top Control Panel.
2. Remove the four small screws holding the trackball bracket from the Control Panel.
3. Note the orientation of the trackball for replacement purposes and push the track-ball from the front to dislodge and remove.

Jog Shuttle [Control Panel]

1. Remove the front cover and top Control Panel.
2. Remove the four small screws holding the jog shuttle circuit board assembly.
3. Pull up on the jog shuttle assembly by only pulling on the board itself to remove. The outer shuttle knob should be held in place by a bracket and does not need to be removed. The center knob will be released.

Keyboard

1. Remove the front cover and top Control Panel.

2. Disconnect the keyboard cable connector located underneath the monitor and tie-wrapped.
3. Slide the keyboard forward.
4. Loosen the two Phillips screws on top of the keyboard.
5. Remove the three Phillips screws from underneath the front keyboard plate and drop the front of the bottom keyboard plate down.
6. Remove the plunger nut (3/8”) underneath the keyboard and slide the plunger back.
7. Remove the two screws (just to the left of the plunger) holding the aluminum bracket and the keyboard spring mechanism.
8. Slide the keyboard out by releasing the catch on each side and underneath the slide brackets by pressing one up and one down.

Keyboard Plunger

1. Remove the front cover and top Control Panel.
2. Slide the keyboard forward.
3. Loosen the two Phillips screws on top of the keyboard.
4. Remove the three Phillips screws from underneath the front keyboard plate.
5. Remove the plunger nut (3/8”) underneath the keyboard and slide the plunger back.
6. With the keyboard forward, remove the two large screws holding the plunger in place and remove the plunger assembly.
7. When reinstalling, note the locking nut and screw at the end of the plunger which may be adjusted for proper tension.

CD ROM drive (**Galaxy™** only)

1. Remove the front cover and top Control Panel.
2. Disconnect the CD ROM cables.
3. Remove the 4 screws (2 on each side) and lift the CD ROM drive up.
4. Remove the 8 small screws (4 on each side) to remove the drive from its holding bracket.

PC

PRECAUTION

Precaution: If the PC or system disk drives are replaced, **Galaxy™** software must be installed and configured by a Boston Scientific Engineer.

Note:

- **Galaxy™** All covers need to be removed and the back panel dropped to replace the PC.
- **Galaxy™2** The PC may be replaced by removing only the front cover.

PC assembly replacement

1. Carefully disconnect all cables from the back of the PC. Although the cables are labeled, it may be helpful to redundantly document their specific location as they are removed.
2. Slide the PC assembly out the front by pushing up on the front levers at each side of the PC.

CAUTION

Caution: Carefully check that all cables attached to the rear of the PC have sufficient slack and can move freely before pulling the PC fully forward. May be necessary to remove the other **Galaxy™ System** covers to confirm.

3. Remove the 12 screws that hold the PC to the brass brackets on the sliders.
4. Remove two hex screws at the bottom sides of the PC to remove the black plastic corners.
5. When reinstalling the PC, carefully check that all cables on the rear of the PC have sufficient slack, are tie-wrapped appropriately as found, and that none of the cables or cable connections have been damaged.

Galaxy™ Hard Disk Drives (HDD)

Note: 9 GB HDD is on the left (facing the PC) and will contain the operating software. The other HDD is the patient data cine-loop drive. **Make note of the jumper settings of the HDD removed and install jumpers to the replacement hard drive exactly the same.**

1. Disconnect the disk drive power supply and data cable. It may be easier to remove the cables after first removing the mounting screws and sliding the drive out towards the front a little. When removing the ribbon cables: 1) be gentle as not to cause damage 2) note the orientation of the ribbon cable (use red stripe as reference) before removing.
2. Remove the four screws (two on top and two on the bottom) and slide the disk drive out towards the front of the PC. To remove the HDD one must first remove the MO disk drive. Then slide the HDD assembly to the right and out the front. When reinstalling the HDD assembly note the 10GB ribbon cable goes to the dual Pentium processor board.

Galaxy™2 Hard Disk Drives (HDD)

1. Pull out the PC, and remove the top cover.
2. Remove all cables attached to the hard drive to be removed.
3. Unscrew 2 screws in the front of the PC holding the HDD.
4. Remove 2 screws on each side of the bracket to allow the removal of the hard drive.

Note: Make note of the jumper settings of the HDD removed and install jumpers to the replacement hard drive exactly the same.

PC Printed Circuit Assemblies (PCA)

CAUTION

Caution: Use a grounding wrist-strap when handling PCA's.

Galaxy™ Refer to drawing 10798-002 to identify the internal components of the PC.

Galaxy™2 Refer to drawing 90041190 to identify the internal components of the PC.

1. To access internal printed circuit boards and sub-assemblies, loosen the screws holding the top plate of the PC and remove the top plate.
2. To remove a PCA, the retaining bar holding the all the boards in place must first be removed. (2 screws, one at each end).
3. To remove a board, remove its holding screw near the edge connector.
4. Although cables are labeled, note the position and location of all cables and connectors prior to disconnecting.
5. With both hands, use a gentle rocking motion while pulling up to remove the PCA.

CR-RW/DVD +RW drive (Galaxy™^{2} only)

1. Remove two screws holding the DVD bracket cover on the right side of the PC chassis.
2. Remove two wing nuts holding the DVD bracket cover in the PC; remove the DVD bracket cover.
3. (Optional) Remove the floppy drive by unscrewing the 2 screws in the front of the PC holding the floppy in place. This will allow easier access to the screws holding the DVD bracket.
4. Remove two screws holding the DVD bracket in place. These are located on the left side of the DVD bracket.
5. Remove all cables attached to the DVD writer.
6. Take out the entire DVD bracket assembly and remove the four screws holding the DVD writer in the bracket; two on each side.

PC Power Supply

1. Disconnect all cable connectors from the power supply going to the disk drives and motherboard.
2. Remove the four holding screws from the back by the fan.

Video Cassette Recorder (VCR)

1. Remove all covers.
2. Drop down the back panel.
3. Remove tie-wraps as needed to gain access.
4. Disconnect all the cables at the back of the VCR and clear a space to pull the VCR out toward the back.
5. Remove the three mounting screws located at the back of the VCR and slide the VCR out the back of the system.

Printer

1. For the replacement of the Mitsubishi CP700/CP770 Printers in **Galaxy™**
    a. Remove all covers.
    b. Drop down the back panel.

c. Remove tie-wraps as needed to gain access.
d. Disconnect all the cables at the back of the printer and clear a space to pull the printer out toward the back.
e. Remove the three mounting screws located at the back of the printer and slide the printer out the back of the system.

2. For the replacement of the Sony UP-D895 Printers in **Galaxy™²**
    a. Remove front and right side covers.
    b. Remove tie-wraps as needed to gain access.
    c. Disconnect all cables at the back of the printer.
    d. Remove the two mounting screws located at the back of the printer, slide the printer slightly towards the back to get out of the mounting slot in the chassis, then lift printer and pull forward to the front of the system to remove.

VME Card Cage

1. To access the VME PCA's remove the front cover. Refer to drawing 11778-007 to identify the internal components of the VME card cage.
2. Remove one screw holding the front plate of the VME card cage and pull the front plate away.

WARNING

Warning: Beware of sharp metal edges when handling the VME Card Cage and front cover.

3. The VME Card Cage contains PCA's that may be removed by bending the retaining tabs slightly and sliding the PCA out the front. The PCB's are from right to left facing the VME Cage:
    a. RF4
    b. Data Acquisition 4
    c. CPU (Force or Dynatem)
    d. High Voltage 3

Note: It may be necessary to use an adapter cable (P/N 51490-001) for **Galaxy™ Systems** using older Force CPU PCA when installing the new type Dynatem CPU PCA into the VME Card Cage.

4. To remove the entire VME Card Cage from the **Galaxy™ System** remove all covers.

5. Remove all the cables from the back except J40,J41,J42. Remove ten screws from the back plate and pull the back plate out.
6. Remove J40, J41, J42.
7. Remove the two screws in front and two screws in the back holding the VME Card Cage in place and slide out of the system.

Monitor (**Galaxy™**)

Note: The monitor assembly is not considered field-replaceable. The extent of the work to be performed on the monitor in the field will be the replacement of the front monitor bezel.

Monitor cover

1. Although not necessary, it will help to loosen the two screws underneath the monitor near the back (drawing 50374-001).
2. Remove the two screws from the back of the monitor cover.
3. Using two hands, gently squeeze the monitor cover or pry up on the back edge (without damaging the cover); tilt back and up.

Front Monitor bezel

1. Behind the bezel from inside the monitor, remove the four corner screws.
2. Disconnect the cable to the power light at the top of the bezel.
3. Tilt bezel forward from the top.
4. Disconnect the bezel board by removing the four screws.
5. Remove the two cables from the bezel board (CN841and CN842).

LCD Display Unit (**Galaxy™^{2}**)

1. Remove all covers.
2. Remove back panel.
3. Remove the top deck control panel.
4. Remove the power cable for the LCD monitor, this connector is on the left side of the flat panel display assembly.
5. Remove all cables connected to the LCD display assembly.
6. Retract control panel cables from the through-hole located on the left side of the flat panel assembly.
7. Remove 6 hex screws holding the flat panel assembly to the chassis, 3 on each side.
8. The LCD panel assembly can then be lifted from the chassis.

Video Splitter (**Galaxy™^{2}**)

1. Remove all covers.
2. Remove rear panel.

3. Remove all cables connected to the video splitter.
4. Remove two 8/32 nuts beneath the video splitter bracket, and remove the video splitter assembly.

Front Caster

1. Restrict the movement of the rear wheels by bracing wheels with 2”X4” wood block. Lift the front end and place a block of wood underneath to raise the caster(s) up off of the floor 2”.
2. The caster is screwed into the **Galaxy™ System** console by way of a large threaded post. Remove the caster by rotating caster post CCW.
3. Remove dust and residue by blowing air inside the threaded holes on the chassis and on the stud of the caster. Keep the blown debris away from the system when working on the casters. Clean both the caster to be installed and the threaded hole with alcohol.
4. Dry all surfaces before applying primer and adhesive.
5. Spray Loctite Primer-T into threaded hole. Make sure all threads are covered.
6. Apply Loctite Threadlocker to the caster stud.
7. Fasten the caster to the chassis by hand screwing in a CW direction until tight.
8. Use a torque wrench set at 420 in.-lb. and tighten the casters until a “clock” sound is heard.

CAUTION

Caution: DO NOT OVERTORQUE.

9. Lower the system, and move the system to an isolated area to allow the adhesive to cure. DO NOT LOCK the two casters or use/move the system for at least 24 hours.

Chapter 9 Parts

Galaxy™ System Parts

Note: The following table lists individual items utilized in Galaxy™ and Galaxy™2. These items may be requested and more specifically identified by contacting Boston Scientific at the following location:

Boston Scientific
47900 Bayside Pkwy.
Fremont, CA 94586
AT&T (800) 949-6708
ivus.techsupport@bsci.com

Galaxy™ System Parts	ZCOM	ZFIN	G1/G2
Super VHS Tape	02182-001	H749021820010	BOTH
Simulator	05408-001	H749054080010	BOTH
PCA Tested HV3-6U **Galaxy™ System**	09434-001	H74909434001S0	BOTH
PCA SOUND 16 BIT SCIMED	09449-001	H749094490010	G1
PCA RS232 Communication SCIMED	09451-001	H749094510010	G1
PCA Data Acquisition SCIMED	09454-001	H749094540010	G1
DISK DRIVE FLOPPY 3.5" 1.44 MB	09838-001	H749098380010	G2
CASTER SWIVEL LOCKABLE 5"	09959-002	H749099590020	BOTH
Trackball 2" Ball PS-2 Teal	10032-001	H749100320010	BOTH
Jog Shuttle	10103-002	H749101030020	BOTH
Control Panel	10122-001	H749101220010	BOTH
Printer Digital CP-700DSU SCIMED	10306-001	H749103060010	G1
Galaxy™ PC sub-assy, Tested	10798-001	H74910798001S0	G1
PCA FRAME GRABBER GENESIS-L-C (Matrox)	10804-001	H74910804001S0	BOTH
DRIVE 5.25" MAGNETO OPTICAL DISK SCIMED	10873-001	H749108730010	G1
PCA Tested, RF4+	11359-001	H74911359001S0	BOTH
PCA Tested UPS AC DISTR GAL SCIMED SPARE	11379-001	H74911379001S0	G1
PCA Tested, ACQ4	11582-001	H74911582001S0	BOTH
UPS 700V	11627-001	H749116270010	BOTH
PCA Un-Tested INTCON SCIMED SPARE	11649-002	H74911649002S0	G1
PCA Tested PBUF **Galaxy™** SCIMED REFURB	11767-001	H74911767001S0	G1
Galaxy™ System VME sub-assy Tested	11778-001	H74911778001S0	BOTH
Monitor EI20 T550 17"	12027-001	H749120270010	G1
ASSY Merlin Panel Box	50006-017	H749500060170	G1
Assy. Isolated Power Supply	50006-018	H74950006018S0	G1
Assy. Top Deck Rear	50078-001		G1

PCA Tested UPS CONTROL GAL SCIMED SPARE	50117-011	H749501170110	G1
PCA UPS Controller, Tested	50117-021	H749501170210	G2
Lemo® cable / internal / VME	50147-001	H749501470010	G1
CABLE LEMO PLUG TO LEMO PLUG 15'	50154-001	H749501540010	G1
CABLE LEMO PLUG TO LEMO PLUG 30'	50154-002	H749501540020	G1
CABLE LEMO PLUG TO LEMO PLUG 60'	50154-003	H749501540030	G1
CABLE LEMO PLUG TO LEMO PLUG 100'	50154-004	H749501540040	G1
Lemo® cable / internal / Merlin	50157-001	H749501570010	G1
PCA Tested PCI SCAN CONV SCIMED SPARE	50180-001	H74950180001S0	BOTH
DRIVE CD R/W 8 X 24 SCSI-2 SCIMED	50267-001	H749502670010	G1
PCA VIDEO CVSRN FCTN SCIMED	50269-001	H749502690010	G1
Scan Converter Extron SCIMED, NTSC	50288-001	H749502880010	G1
Scan Converter Extron SCIMED, PAL	50288-002	H74950288002R0	G1
PCA Scan Conv. Extron, **Galaxy™²** (NTSC)	50288-003	H749502880030	G2
PCA Tested ISOLATION GAL SCIMED SPARE	50317-001	H74950317001S0	G1
PCA Intel Pro/100+ Adapter SCIMED	50348-001	H749503480010	G1
VCR NTSC SVHS AG-MD830P SCIMED	50364-001	H749503640010	G1
PCA CPU Board Dual SCIMED	50389-001	H749503890010	G1
PCA Tested CPU 68000 (Force)	50391-001	H74950391001R0	BOTH
Assy CA BNC Pl TO BNC PL 75 Ohm 2.5Ft		H749504450010	G1
Assy CA BNC Pl TO BNC PL 75 Ohm 5Ft		H749504460010	G1
Assy CA BNC Pl TO BNC PL 75 Ohm 1.5Ft		H749504470010	G1
DISC DR HARD 9.2 GB SCIMED	50557-001	H749505570010	G1
DISC DRIVE HARD 18.4 GB SCIMED	50557-002	H749505570020	G1
PCA ULTRA160 SCSI HOST ADAPTER	50558-001	H749505580010	G1
VCR NTSC SVHS AG-MD835P		H749511030010	BOTH
SCSI cables / PC Round Internal	51174-001		G1
Keyboard Elastomer MKER-84	51176-001	H749511760010	G1
SCSI cable / external	51181-001	H749511810010	G1
SCSI cables / external CD-ROM	51182-001	H749511820010	G1
Flat Panel Display	51328-001	H74951328001S0	G2
ASSY CA VME REAR BRACKET TO CPU PCA	51411-001	H749514110010	G1
PCA Tested CPU DCPU2-S2 VME	51419-001	H749514190010	G1
Splitter, Video, MSV-XXXE 150Mhz	51495-002	H74951495002R0	G2
ASSY HARNESS LCD/P4	90042558-01	H749900425580	G2
Assy Computer P4 Tested **Galaxy™²**	90041190-01	H74990041190S0	G2
DICOM Quick Ref. Card, **Galaxy™ System**	90048063-08		G1
PCA PCI ADAC/5500 SERIES, DATA ACQ		H749516230000	G2
DISC DRIVE DVD-R/RW HP DVD200i	N/A	H749516240000	G2
Disc Drive Hard 120GB IDE	N/A	H749516250000	G2
PCA MOTHERBOARD INTEL P4		H749516260000	G2
MEM SDRAM 184PIN UNBUFF (64MBX64MB) 512MBDDR	N/A	H749516270000	G2

Printer SONY Digital UP-D895		H749516280000	G2
IC CPU INTEL P4 2.4 GHz	N/A	H749516290000	G2
PCA PCI SERIAL PORT 4000RJ		H749516300000	G2
ASSY CA IDE 40P 2 CONN ROUND 12"	N/A	H749516330000	G2
ASSY CA FDD 2 CONN ROUND 10"	N/A	H749516340000	G2
ASSY CA IDE 40P 3 CONN ROUND 12"	N/A	H749516350000	G2
Fan 12 VDC 120X120X25mm 69 CFM	N/A	H749516360010	G2
BLOWER, 12VDC, 42 CFM	N/A	H749516370010	G2
POWER SUPPLY, PC, ATX, 420W	N/A	H749516380010	G2
Assy Wheel Left		H749900412420	BOTH
Assy Wheel Right		H749900412440	BOTH
Sterile Pullback Sled	N/A	H749A70200	BOTH
Sheaths		H749A70250	G1
Double Cover Sterile MD5	N/A	H749A70260	G2
Media, DVD+RW 4.7GB	N/A	H749A70310	BOTH
Media, CD-RW 700MB		H749A70320	BOTH
Printer Paper, Mitsubishi 700DS/770DW		H749A70350	BOTH
DICOM Configuration Guide (Japanese)		H749A70570	G1
Galaxy™ Technical Update Guide (Japanese)		H749A70700	G1
MD5 Motordrive Unit	N/A	H749I50330	BOTH
Knob, adjustment, LCD **Galaxy™²**	51361-001	H749513610010	G2
Plate, Pocket MD5	50007-149	H749500071490	BOTH
PCA Tested HV3-6U (New release)	09434-011	H74909434011S0	BOTH
PCA Tested RF4+ (New release)	11359-011	H74911359011S0	BOTH
PCA Tested ACQ4 (New Release)	11582-011	H74911582011S0	BOTH
Tested VME Assy (New release)	90041243-01	H7499004124301S0	BOTH
Assy Rocker Switch to AC Cont/Dist	90075305-01	H74990075305010	G2
Shipping Crate, **Galaxy™²**	51413-001	H749514130010	G2
Assy Computer P4 Tested **Galaxy™²**	90041190-01	H7499004119001	G2
Ribbon Cable (CA IDC 100p to IDC 50P 2x)	11273-001		G2
Merlin Box (includes VIF)	90095213-01		BOTH
Svc Spare AC Ctrl/Distribution **Galaxy™ System**	90062267-01	H7499006226701S0	Both

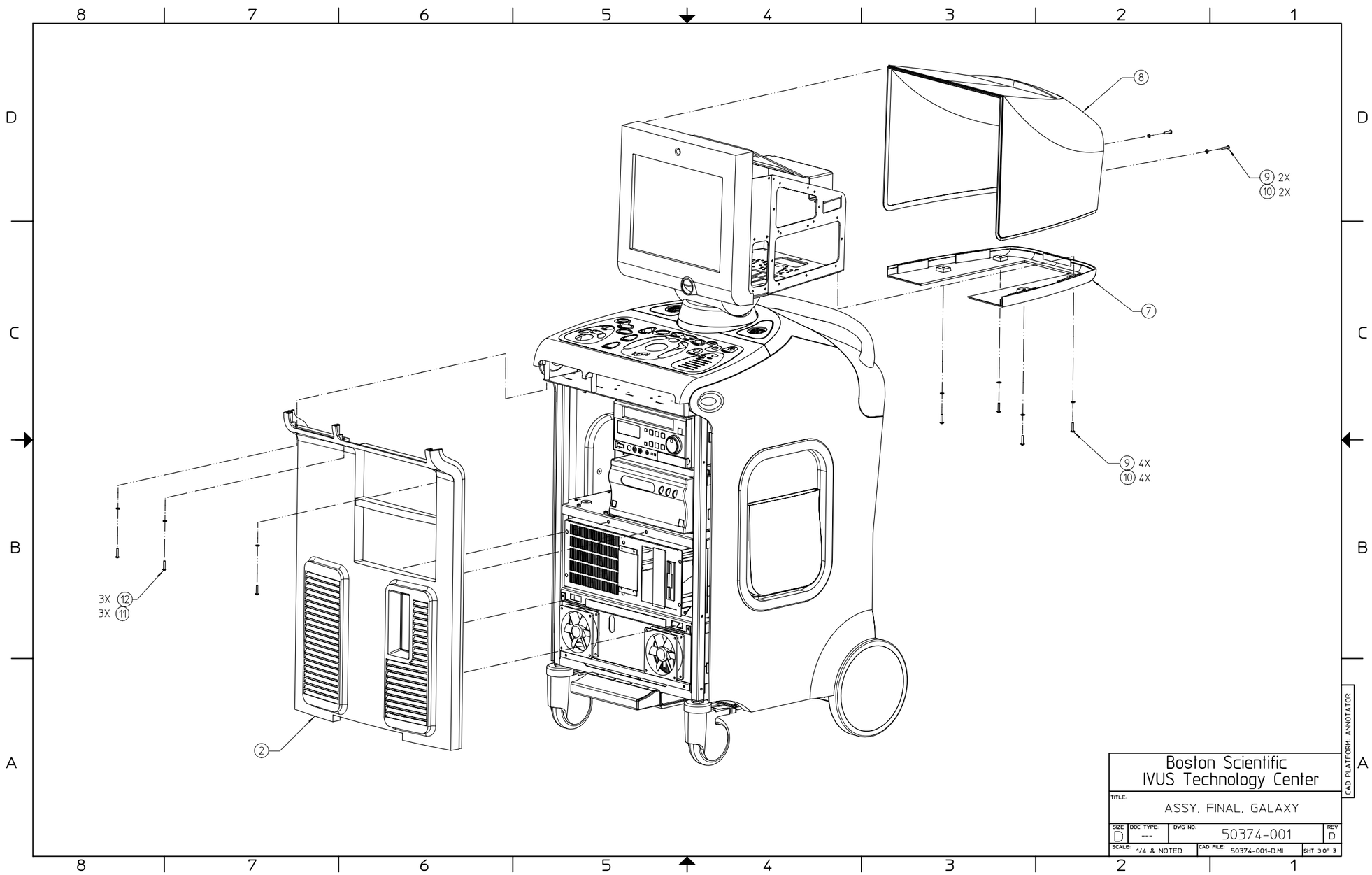
Galaxy™ System Accessories

Note: Some of the items listed below may also be found listed in the previous table. Please note that usable or disposable accessories should be requested from Boston Scientific at the following location:

Boston Scientific Corporation
Marina Bay Customer Fulfillment Center
500 Commander Shea Blvd.
Quincy, MA 02171
(800) 832-7822

Accessory	
Description	Catalog No.
Motordrive (MD5)	H749I50330
Sterile Pullback Sled	H749A70200
Sterile Motordrive Bag	H749A70250 / H749A70260
Blank SVHS Videotape	H749021820010
Printer Paper Roll	H749A70350
CD-R Disk	H749A70320
Magneto-Optical Disk	H749A70310
Imaging Phantom	H749029710010
Catheter Simulator	H749054080010
User's Guide (English):	H749A70330
DICOM Configuration Guide	H749A70630
Galaxy™™ Quick Set Up	US SCI 2181D
Galaxy™™ Training Video	US SCI 2316
CPT Codes 2001	US SCI 2047
ABC's of IVUS CD-ROM	US SCI 2239

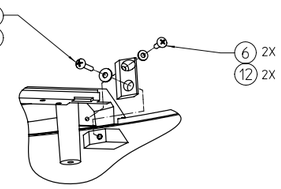
NOTE: The components listed above are the only authorized accessories.



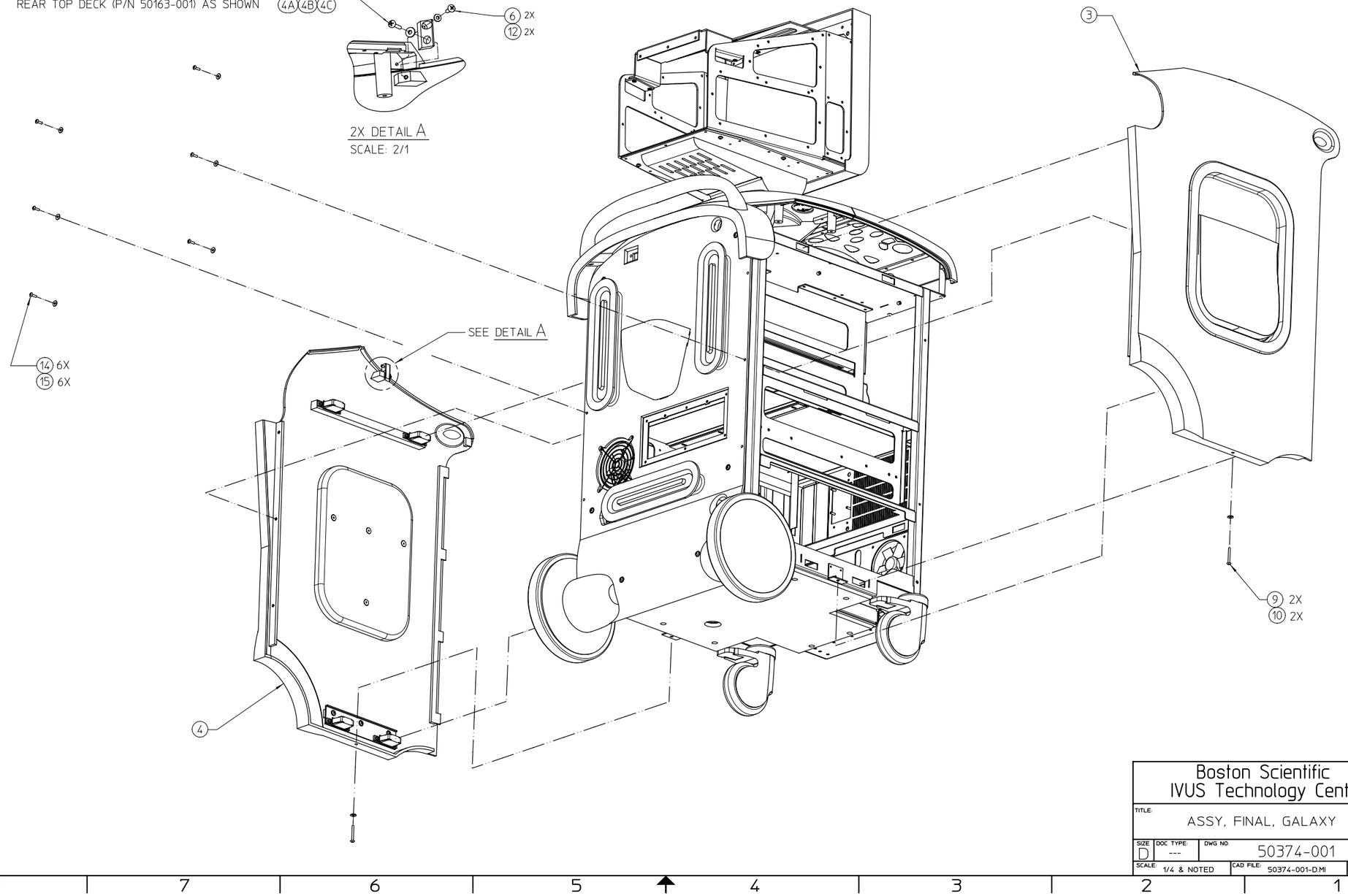
Boston Scientific IVUS Technology Center	
TITLE:	ASSY, FINAL, GALAXY
SIZE: D	DOC TYPE: ---
DWG NO.	50374-001
REV: D	
SCALE: 1/4 & NOTED	CAD FILE: 50374-001-D.MI
SHT 3 OF 3	

CAD PLATFORM ANNOTATOR

MOUNT BLOCK ASSEMBLY TO SIDE PANEL &
REAR TOP DECK (P/N 50163-001) AS SHOWN



2X DETAIL A
SCALE: 2/1



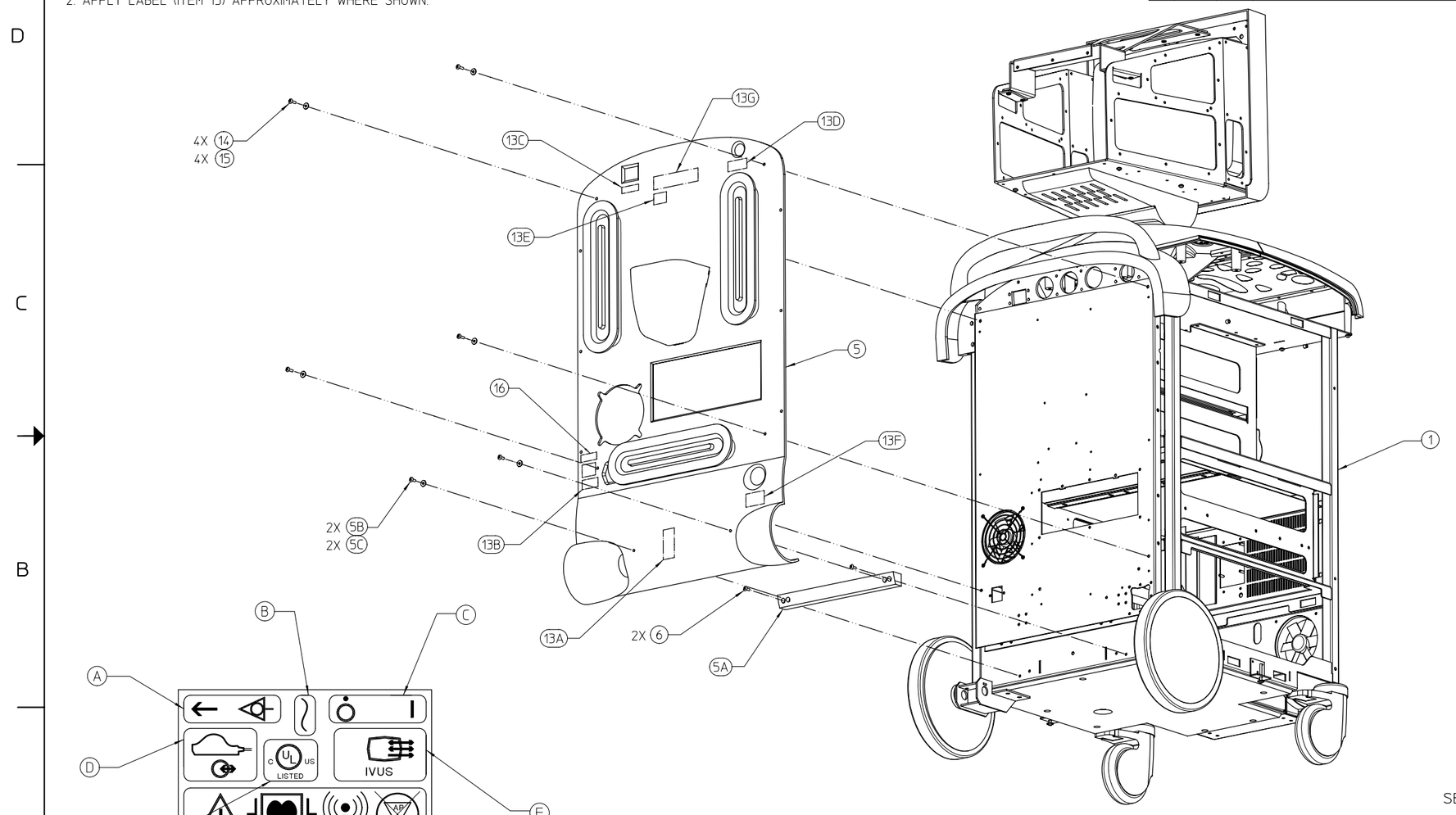
Boston Scientific IVUS Technology Center				
TITLE: ASSY, FINAL, GALAXY				
SIZE: D	DOC TYPE: ---	DWG NO: 50374-001		REV: D
SCALE: 1/4 & NOTED		CAD FILE: 50374-001-D.MI		SHT 2 OF 3

CAD PLATFORM: ANNOTATOR

NOTES: (UNLESS OTHERWISE SPECIFIED).

1. SOME PARTS OF (ITEM 1) OMITTED FOR CLARITY.
2. APPLY LABEL (ITEM 13) APPROXIMATELY WHERE SHOWN.

REVISIONS AUTHORIZATIONS							
REV	DCO	BY	DESCRIPTION	CHECKED	DATE	APPROVED	DATE
B	115256	QT	ADD ITEMS 14 & 15.				
C	119430	QT	CHANGE ITEM 13				
D	124333	QT	ADD ITEM 16 & REVISE HARDWARE				



ITEM 13

SEE SEPARATE P/L

UNLESS OTHERWISE SPECIFIED
ALL DIMENSIONS ARE IN INCHES. [ ] ARE IN MILLIMETERS PER ASME/ANSI Y14.5M
TOLERANCES ARE:

FRACTIONS	DECIMAL	METRIC
± 1/32	.X± .1	X± 1.5mm
	.XX± .01	.X± 1mm
ANGLES	.XXX± .005	.XX± .05mm
±1°	.XXXX± .0005	.XXX± .005mm

SURFACE FINISH

DEBURR AND BREAK ALL SHARP EDGES

THIRD ANGLE PROJECTION

DO NOT SCALE DRAWING

APPROVALS	DATE
DRAWN BY: L. ELLISON	06-13-00
DESIGN: J. SAGASTEGUI	06-13-00
CHECKED:	
APPROV. ENGR:	

LINKED 3D CAD FILE: 50374-001_final_assy.pkg

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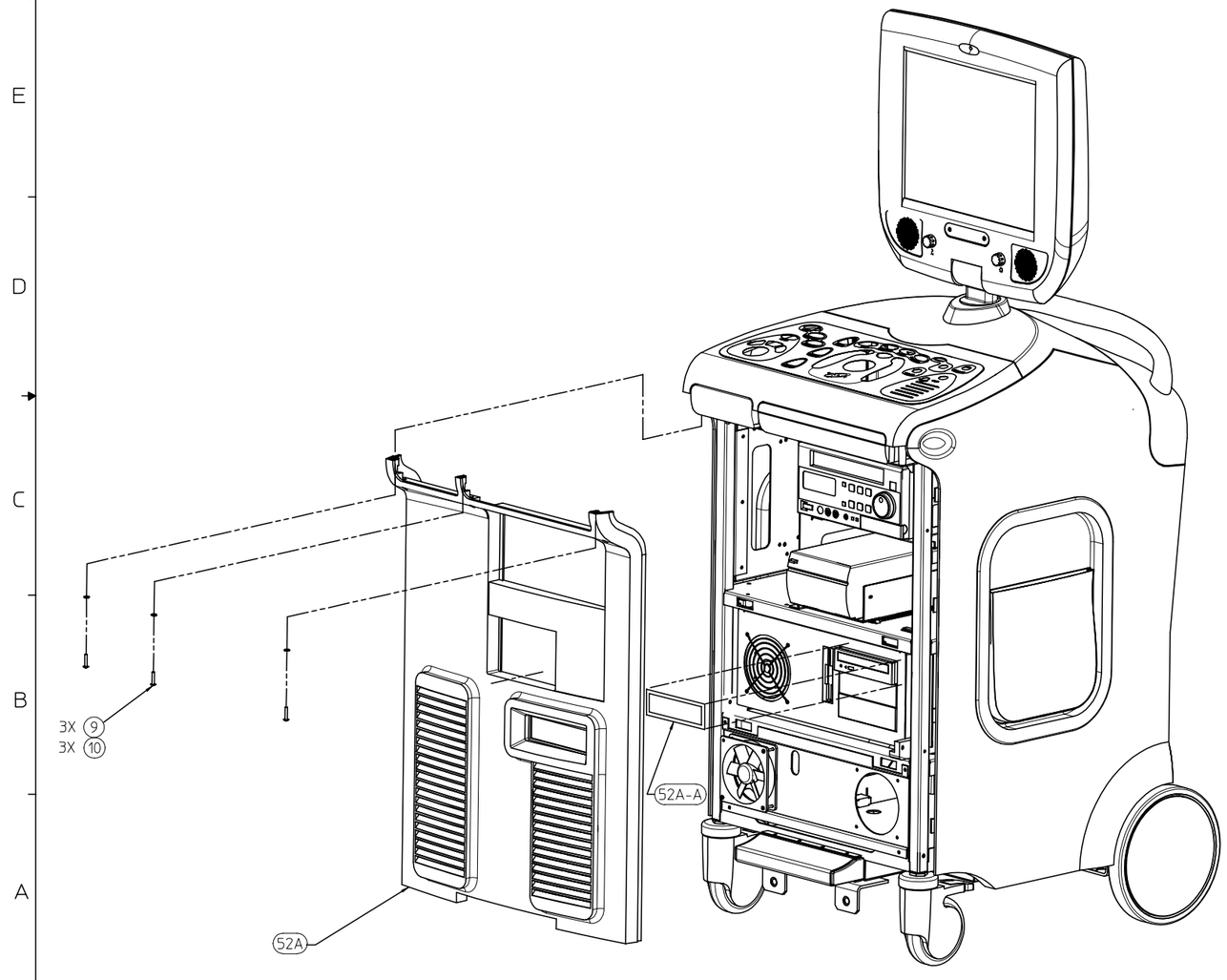
Boston Scientific
IVUS Technology Center

TITLE: ASSY, FINAL, GALAXY

SIZE	DOC TYPE:	DWG NO.	REV
D	---	50374-001	D

SCALE: 1/4 & NOTED | CAD FILE: 50374-001-D.MI | SHT 1 OF 3

CAD PLATFORM: ANNOTATOR



INTERCONNECT TABLE				
BOM ITEM NUMBER	HARNESS ASSY NUMBER	INDIVIDUAL CABLE ASSY NUMBER	FROM	TO
(44)	90042558-01	90043803	PC LVDS	VME LVDS
(44)		90039764	PC COM3	VME APD
(44)		90039758	PC COM1	VME RS232
(44)		90039750	KEYBOARD	PC KEYBOARD
(44)		90039751	CONT PCA J6	PC MOUSE
(44)		90039760	CONT PCA J7	PC COM2
(44)		90039752	CONT PCA J4	PC PWR OUT
(44)		90039752	VID SPLTR	VID SPLTR DC 9V
(44)		90039766	VCR RS232 IN	PC COM5
(44)		90039739	TB3-1B(GRN)/-5B(WHT)/ -16B(BLK)	PC PWR
(44)		90039757	PC LPT1	PRINTER
(44)		90039763	PC MIC.	VCR MIC. LCD MIC.
(44)		51181-001	PC MERLIN	MERLIN ISLN PNL J2
(44)		90039768	PC MATROX	VID SPLTR PC
(44)		90039769	PC MERLIN	VID SPLTR MON3
(44)		90039762	SPRKS/ VCR AUD IN CH-1/CH-2	PC AUD OUT
(44)		90039761	VCR AUD OUT CH-1/CH-2	PC AUD IN
(44)		90039759	ISLN PNL PCA LAN	PC LAN
(44)		90039765	UPS CONT PCA J5	PC COM4
(44)		90039767	ISLN PCA J11	PC COM6
(44)		90039755	PC ADAC	ISLN PCA 12/ UPS CONT PCA J2
(44)		90039749	ISLN PCA J19	PC MATROX VIDEO
(44)		10922-001	ISLN PCA J16	VCR VID OUT
(44)		11131-001	ISLN PCA J6	VME J43
(44)		11131-001	ISLN PCA J8	VME J42
(44)		11131-001	ISLN PCA J12	VME J41
(44)		11131-001	ISLN PCA J14	VME J40
(44)		90039741	VCR S-VID OUT	ISLN PCA J18
(44)	90042558-01	90043362	SCAN CONV	VCR S-VID IN
(1) REF	51004-001	51004-001	VME PS	TB3-3B(GRN)/-8B(WHT)/-13B(BLK)
(1) REF	51003-001	51003-001	ISLN PS	TB3-3C(GRN)/-8C(WHT)/-13C(BLK)
(1) REF	11227-004	11227-004	VCR	TB3-4C(YEL/GRN)/-9C(BLU)/-14C(BRN)
(1) REF	11227-003	11227-003	PTR	TB3-2B(YEL/GRN)/-7B(BLU)/-12B(BRN)
(1) REF	SEE 50288-XXX	(EXTRON VID. CABLE)	SCAN CONVERTER-INPUT	VIDEOSPLITTER-MON 3
(1) REF	11227-002	11227-002	TB3-4B(YEL/GRN)/-9B(BLU)/-14B(BRN)	SCAN CONV.
(1) REF	90045619-01	90045619-01	TB3-1C(GRN)/-5C(WHT)/-16C(BLK)	LCD

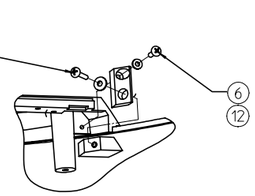
CAD PLATFORM: ME 10

TITLE: ASSY, FINAL, GALAXY 2 (PH)

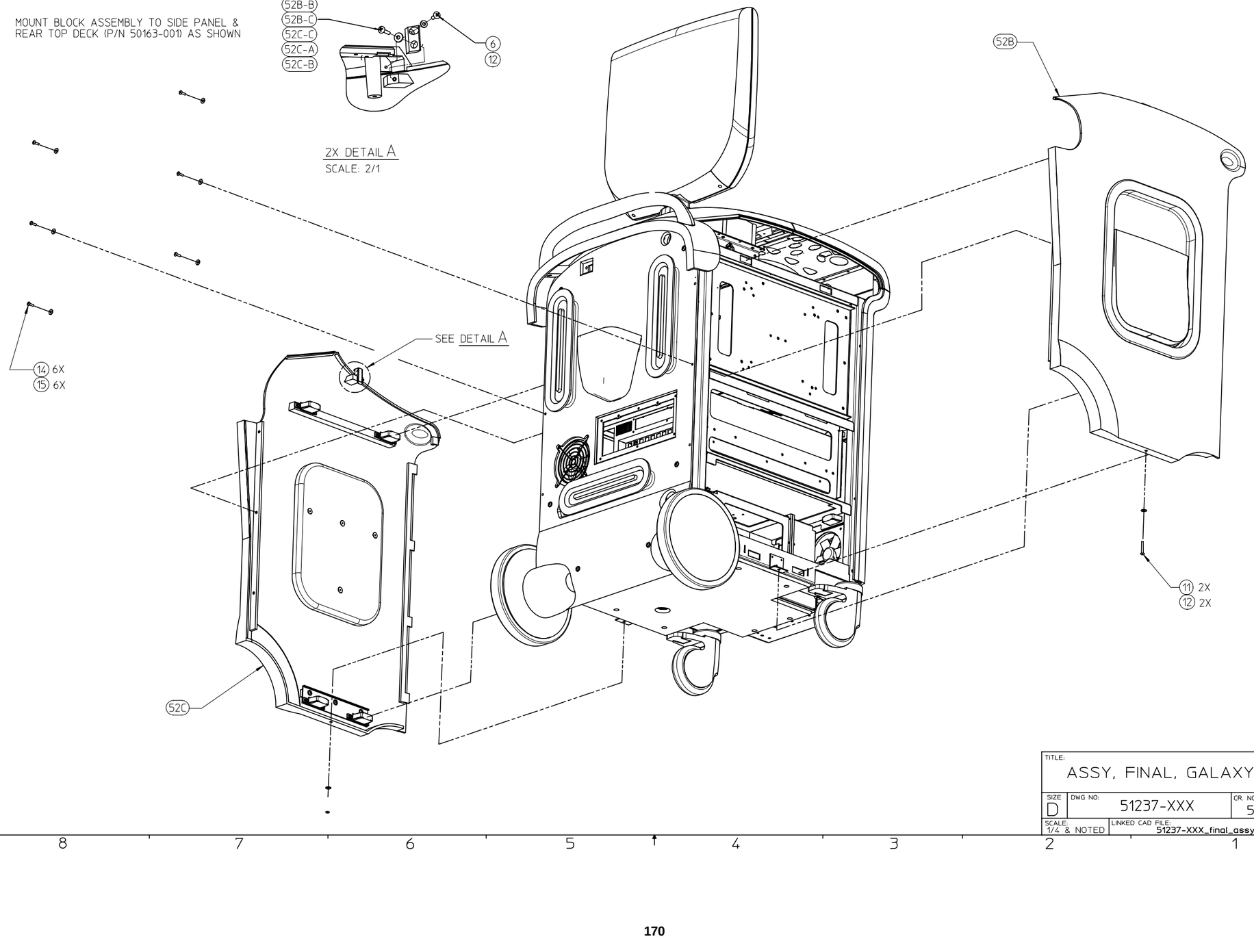
SIZE	DWG NO:	CR. NO.	VER
D	51237-XXX	546592	AE
SCALE: 1/4 & NOTED	LINKED CAD FILE: 51237-XXX_final_assy.pkg		SHT 4 OF 4

MOUNT BLOCK ASSEMBLY TO SIDE PANEL &
REAR TOP DECK (P/N 50163-001) AS SHOWN

52B-A
52B-B
52B-C
52C-C
52C-A
52C-B

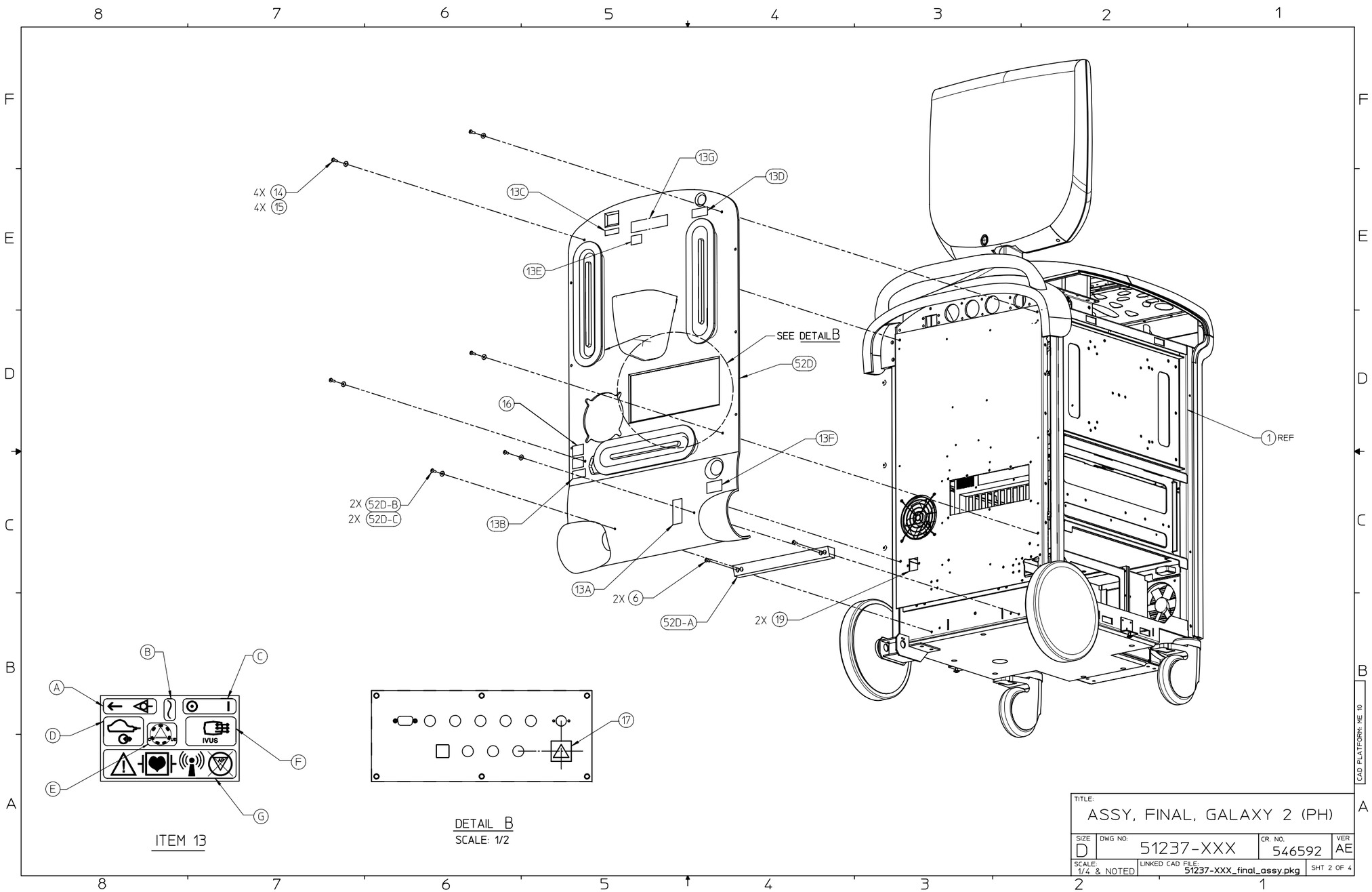


2X DETAIL A
SCALE: 2/1



CAD PLATFORM: ME 10

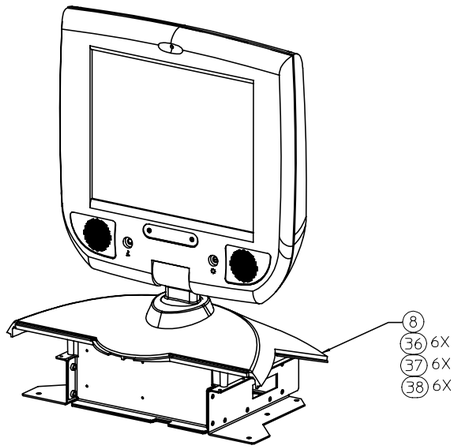
TITLE: ASSY, FINAL, GALAXY 2 (PH)			
SIZE: D	DWG NO: 51237-XXX	CR. NO. 546592	VER: AE
SCALE: 1/4 & NOTED	LINKED CAD FILE: 51237-XXX_final_assy.pkg		SHT 3 OF 4

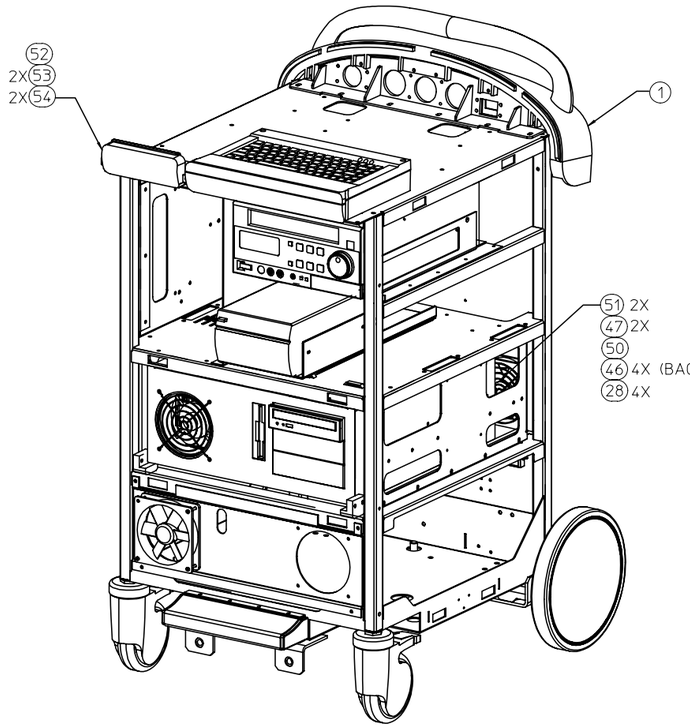

4X 14
4X 15
13G
13D
13C
13E
SEE DETAIL B
52D
16
13F
2X 52D-B
2X 52D-C
13B
13A
2X 6
52D-A
2X 19
1 REF
B
C
E
D
A
IVUS
17
ITEM 13
DETAIL B
SCALE: 1/2
CAD PLATFORM: ME 10
TITLE:
ASSY, FINAL, GALAXY 2 (PH)
SIZE D
DWG NO: 51237-XXX
CR. NO. 546592
VER AE
SCALE: 1/4 & NOTED
LINKED CAD FILE: 51237-XXX_final_assy.pkg
SHT 2 OF 4

NOTES : (UNLESS OTHERWISE SPECIFIED)

1. IN ALL VIEWS, SOME PARTS ARE OMITTED FOR CLARITY.

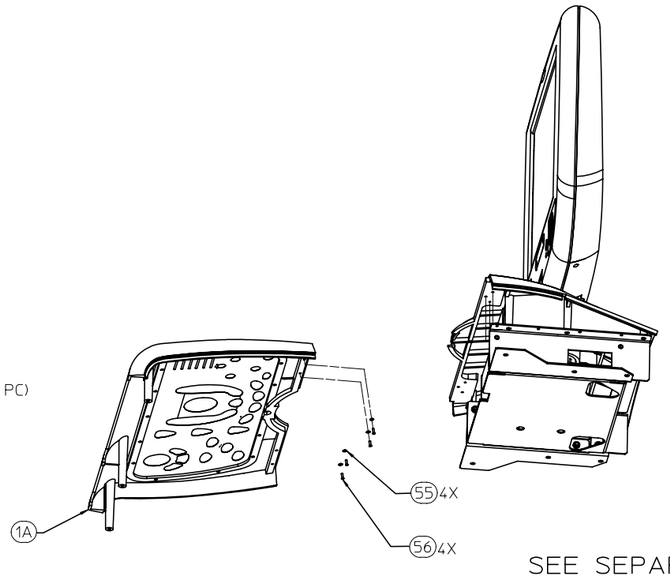
2. APPLY THREADLOCKER (ITEM 22) TO ALL FASTENERS PRIOR TO INSTALLATION.





MATERIAL TABLE

DASH	REV	DESCRIPTION
001	E	ASSY, FINAL GALAXY 2 120V NTSC DMSTC
002	08	ASSY, FINAL GALAXY 2 100V NTSC JAPAN
003	08	ASSY, FINAL GALAXY 2 230/240V PAL EURO
004	08	ASSY, FINAL GALAXY 2 220V NTSC EXPRT
006	08	ASSY, FINAL GALAXY 2 220V PAL EXPRT



SEE SEPARATE P/L

FORMAT NO.: 90046053 Ver. AA

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED
ALL DIMENSIONS ARE IN INCHES & MILLIMETERS [ ] PER ASME/ANSI Y14.5M
TOLERANCES ARE:
FRACTIONAL INCHES ±1/32 MILLIMETERS X ±.1 XX ±.01 X ±0.1mm
ANGULAR ±1° XXX ±.005 XX ±0.01mm XXXX ±.0005
DO NOT SCALE DRAWING
SURFACE FINISH

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APPROVALS	DATE
DRAWN BY M.RAMOS	06/14/02
CHECKED.	
ENGR/DESGR: T.PHAM	06/13/00

DEBURR AND BREAK ALL SHARP EDGES

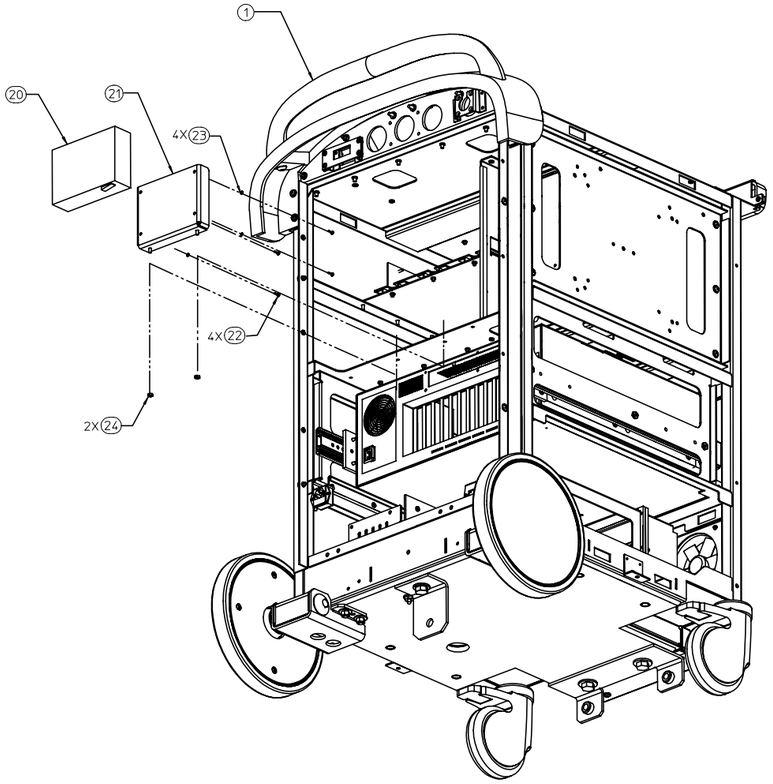
Boston Scientific

TITLE: ASSY, FINAL, GALAXY 2 (PH)

SIZE D | DWG NO: 51237-XXX | CR. NO. 546592 | VER AE

SCALE: 1/4 & NOTED | LINKED CAD FILE: 51237-XXX_final_assy.pkg | SHT 1 OF 4

CAD PLATFORM: ME 10



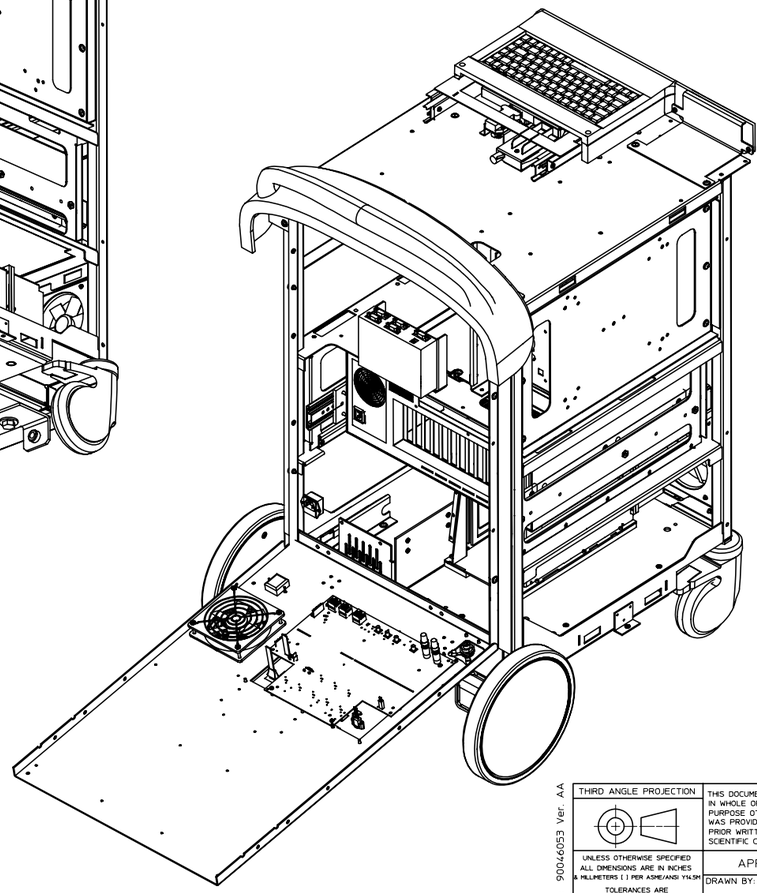


TABLE 1

THREAD SIZE	MATERIAL	AT (in.lb.) *	AT (in.lb.) **
6-32 UNC	SST	9.6	6.7
8-32 UNC	SST	20	14
2-56	SST	2.5	1.8
4-40	SST	5.2	3.6

* CONDITION: SCREWS HOLDING 2 OR MORE PIECES OF METAL TOGETHER, WITH NO NON-METALLIC MATERIALS BETWEEN.

** CONDITION: SCREWS HOLDING 2 OR MORE PIECES OF METAL TOGETHER, WITH NON-METALLIC MATERIALS THREAD INTO METAL.

INTERCONNECT TABLE

FROM	TO	ITEM #
VIDEO I/O BRKT	MERLIN ISO PNL	5
FAN	ISOLATED P.S.	6
ISO PCA-J10	ISO PANEL	7
ISO PCA-J20	ISO PANEL	8
ISO PNL PCA-J22	ISOLATED P.S.	19
TERMINAL BLOCK 3	MONITOR	25

SEE SEPARATE P/L

MATERIAL TABLE		
DASH	REV	DESCRIPTION
001	B	ASSY. ELECTROMECHANICAL IV, GALAXY 2 (PH)

FORMAT NO.: 90046053 Ver. AA

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED ALL DIMENSIONS ARE IN INCHES & MILLIMETERS [ ] PER ASME/ANSI Y14.5M

TOLERANCES ARE

FRACTIONAL INCHES ±1/32 — MILLIMETERS X ±.1, XX ±.01, X ±0.1mm

ANGULAR ±1° — XXX ±.005, XX ±0.01mm, XXXX ±.0005

DO NOT SCALE DRAWING

SURFACE FINISH: ____

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APPROVALS	DATE
DRAWN BY: M.RAMOS	04/25/02
CHECKED:	
ENGR/DESGR T.PHAM	02/02/00
DEBURR AND BREAK ALL SHARP EDGES	

Boston Scientific

TITLE: ASSY, ELECTROMECHANICAL IV, GALAXY 2 (PH)

SIZE D | DWG NO: 51236-000 | CR. NO. 543541 | VER AB

SCALE: 1/4 & NOTED | LINKED CAD FILE: 51236-000.pkg | SHT 1 OF 2

CAD PLATFORM: ANNOTATOR

VER	CR#	DESCRIPTION	NAME	DATE
02	02-0946	INITIAL RELEASE OF ASSEMBLY DRAWING.		7/03/02
03	528757	REVISED BOM ITEM 3, 4 & 13, DELETED ITEM 7, 8 & 16, RE-NUMBERED ITEMS	T.PHAM	10/17/02
04	530525	ITEM 1, 90045954-01 WAS 50006-003	T.PHAM	10/25/02
AA	532987	INITIAL PRODUCTION RELEASE. VER. CHANGE ONLY & BOM CHANGE P/N ON ITEM 11.	E.VAZQUEZ	12/12/02

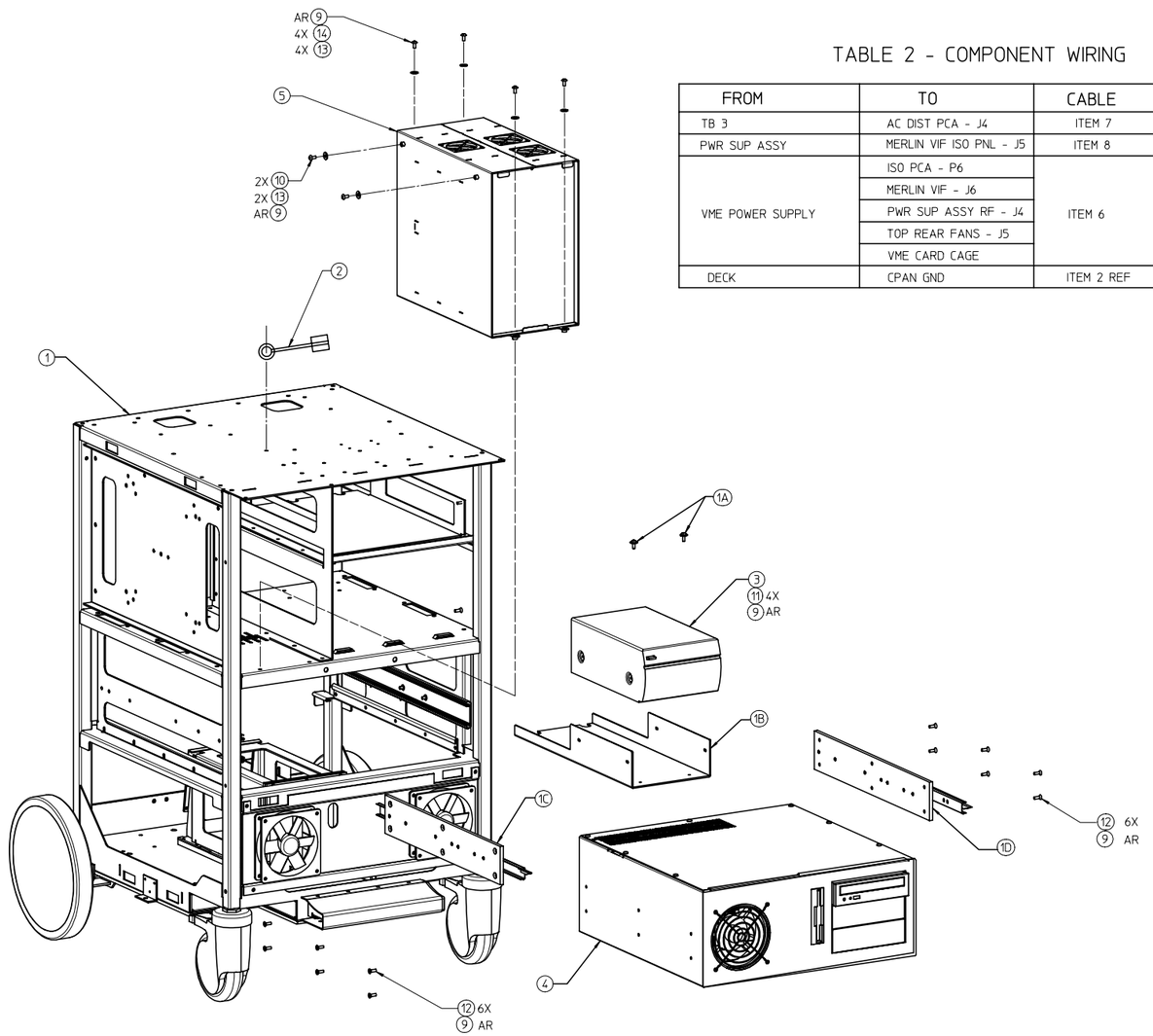


TABLE 2 - COMPONENT WIRING

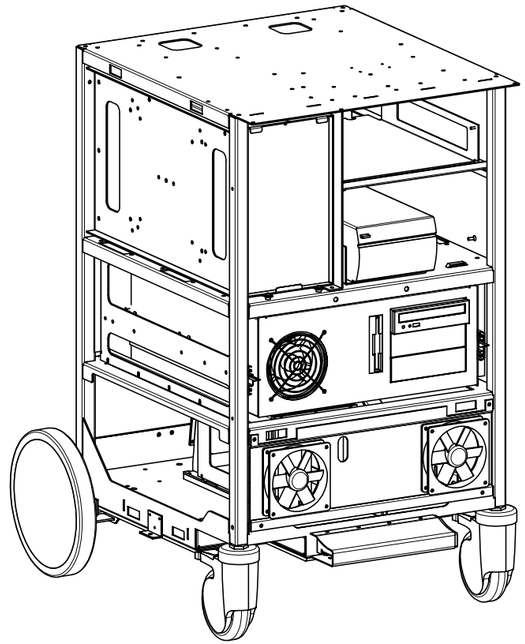
FROM	TO	CABLE	COMMENTS
TB 3	AC DIST PCA - J4	ITEM 7	
PWR SUP ASSY	MERLIN VIF ISO PNL - J5	ITEM 8	OPEN FOR F.S.
VME POWER SUPPLY	ISO PCA - P6	ITEM 6	
	MERLIN VIF - J6		OPEN FOR F.S.
	PWR SUP ASSY RF - J4		
	TOP REAR FANS - J5		
	VME CARD CAGE		
DECK	CPAN GND	ITEM 2 REF	

TABLE 1

THREAD SIZE	MATERIAL	AT (in.lb.) *	AT (in.lb.) **
8-32 UNC	SST	20	14
10-32 UNC	SST	32	22

* CONDITION: SCREWS HOLDING 2 OR MORE PIECES OF METAL TOGETHER, WITH NO NON-METALLIC MATERIALS BETWEEN.

** CONDITION: SCREWS HOLDING 2 OR MORE PIECES OF METAL TOGETHER, WITH NON-METALLIC MATERIALS THREAD INTO METAL.



SEE SEPARATE P/L

MATERIAL TABLE			
DASH	REV	CR#	DESCRIPTION
001	A	532987	ASSY, ELECTROMECHANICAL 1, GALAXY

FORMAT NO: 02178-000 VER: AB

THIRD ANGLE PROJECTION

DO NOT SCALE DRAWING

UNLESS OTHERWISE SPECIFIED
ALL DIMENSIONS ARE IN INCHES. [ ] ARE IN MILLIMETERS PER ASME/ANSI Y14.5M
TOLERANCES ARE:

FRACTIONS	DECIMAL	METRIC
±	.X ± .1	X ± 1.5mm
	.XX ± .01	X ± .1mm
ANGLES	.XXX ± .005	.XX ± .05mm
± 1°	.XXXX ± .0005	.XXX ± .005mm

SURFACE FINISH

DEBURR AND BREAK ALL SHARP EDGES

APPROVALS	DATE
DRAWN BY: T. PHAM	10-02-02
CHECKED:	
APPROV. ENGR: T. PHAM	10-02-02

LINKED 3D CAD FILE: 51214-001_em_assy_1.pkg

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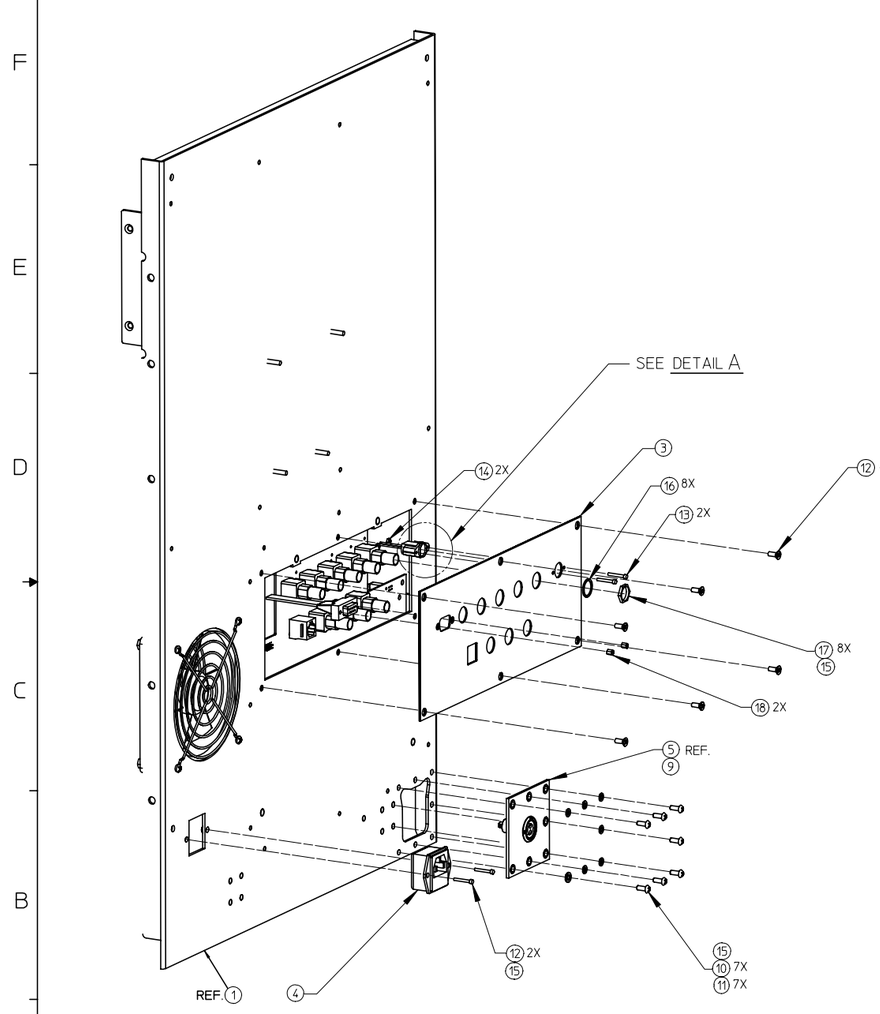
Boston Scientific

TITLE: ASSY, LCD ELECTROMECHANICAL I, GALAXY

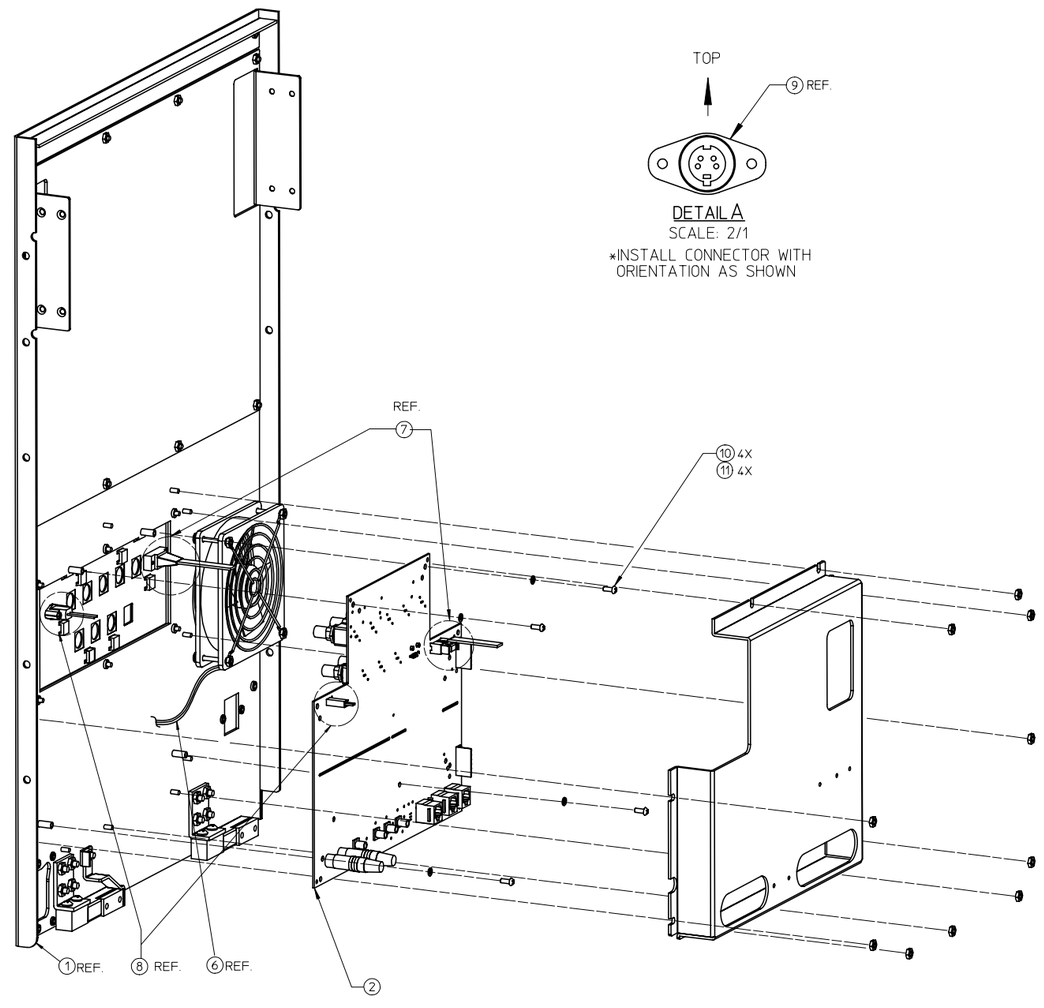
SIZE	DOC TYPE.	DWG NO.	VER
D	ZWC	51214-001	AA

SCALE: 1/4 | CAD FILE: 51214-001-AA.MI | SHT 1 OF 1

CAD PLATFORM: ANNOTATOR



VIEW-1
Scale 1/2
(SOME ITEMS ARE NOT SHOWN FOR VIEWING CLARITY)



VIEW-2
Scale 1/2
(SOME ITEMS ARE NOT SHOWN FOR VIEWING CLARITY)

DETAIL A
SCALE: 2/1
*INSTALL CONNECTOR WITH ORIENTATION AS SHOWN

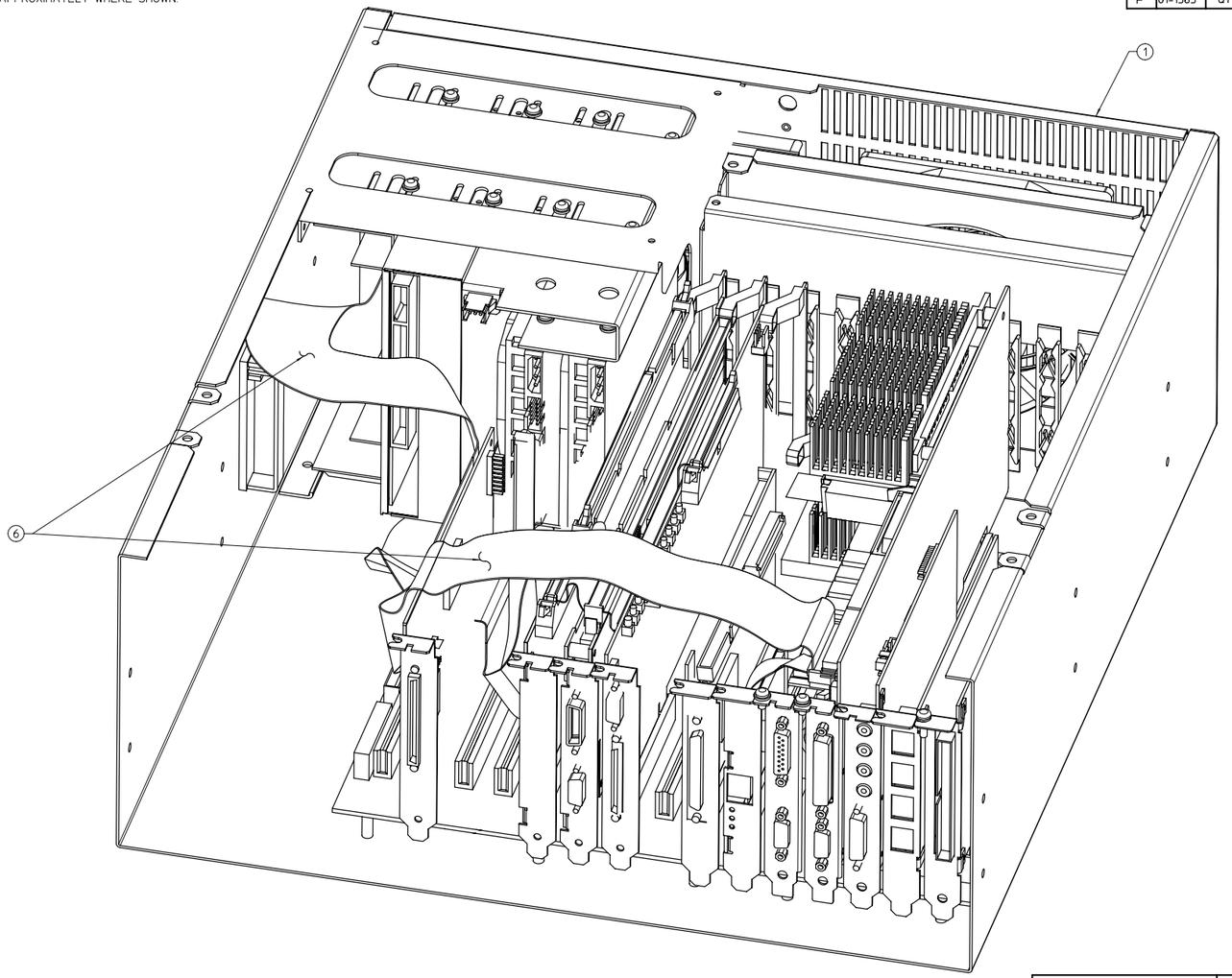
CAD PLATFORM: ANNOTATOR

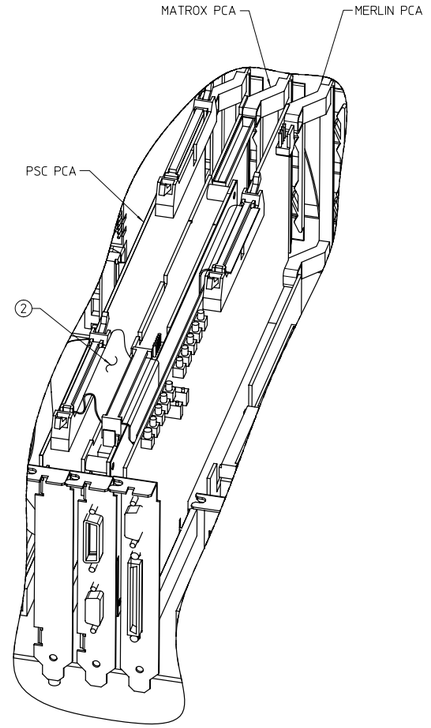
TITLE: ASSY, ELECTROMECHANICAL IV, GALAXY 2 (PH)			
SIZE: D	DWG NO: 51236-000	CR. NO. 543541	VER: AB
SCALE: 1/4 & NOTED	LINKED CAD FILE: 51236-001.pkg		SHT 2 OF 2

NOTES: (UNLESS OTHERWISE SPECIFIED):

1. POWER SUPPLY, CHASSIS REAR PANEL AND SOME SLOT PLATES NOT SHOWN FOR CLARITY.
2. CONNECT CABLES APPROXIMATELY WHERE SHOWN.

REVISIONS AUTHORIZATIONS							
REV	DCO	BY	DESCRIPTION	CHECKED	DATE	APPROVED	DATE
D	01-1197	QT	ITEM 7 CHANGED IN BOM.				
E	01-1335	QT	UPDATE REVISION TO TRACK WITH BOM				
F	01-1363	QT	REVISE SHEETS 1 & 2 AND ADD SHEET 3.				





SEE SEPARATE P/L

UNLESS OTHERWISE SPECIFIED ALL DIMENSIONS ARE IN INCHES, [ ] ARE IN MILLIMETERS PER ASME/ANSI Y14.5M TOLERANCES ARE: FRACTIONS DECIMAL METRIC ± 1/32 .X± .1 X± 1.5mm ANGLES .XX± .01 X± .1mm ±1° .XXX± .005 XX± .05mm .XXXX± .0005 XXX± .005mm	APPROVALS	DATE	Boston Scientific IVUS Technology Center
	DRAWN BY: TOLEDO	03-28-00	
	DESIGN: P. MYERS	03-28-00	TITLE: ASSY, CABLES, PC, GALAXY
	CHECKED:		
	APPROV. ENGR:		
	LINKED 3D CAD FILE: 10798_001_pc_assy.pkg		SIZE: D DOC TYPE: --- DWG NO: 10798-003 REV: F
THIRD ANGLE PROJECTION	VIEWS: 10798-003		SCALE: 8/10 CAD FILE: 10798-003-F.MI SHT 1 OF 3
DO NOT SCALE DRAWING	DEBURR AND BREAK ALL SHARP EDGES		

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FORMAT NO. XUS-0275-00B SIZE A4

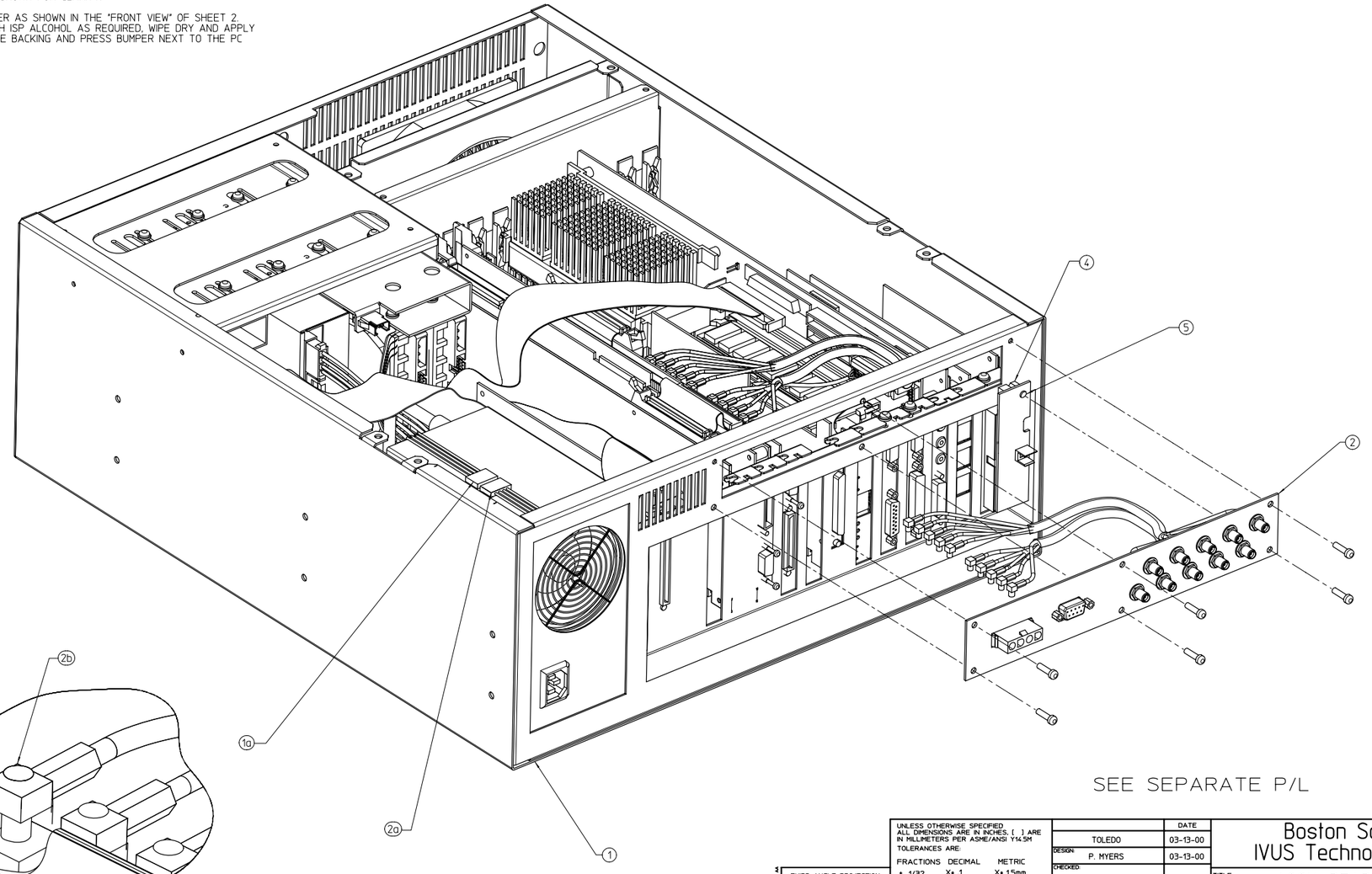
CAD PLATFORM: ANNOTATOR

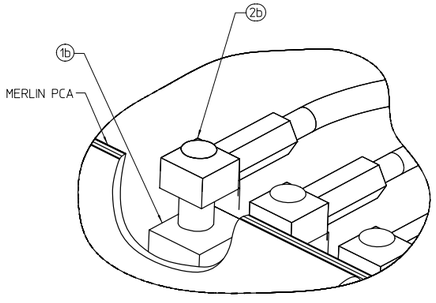
NOTES. (UNLESS OTHERWISE SPECIFIED):

1. USING EXISTING HARDWARE, INSTALL ITEMS 3.
2. APPLY THREAD LOCKER (ITEM 6) TO ALL HARDWARE PRIOR TO INSTALLATION.
3. VARIOUS CABLES NOT SHOWN FOR CLARITY.
4. INSTALL ITEM 9, BUMPER AS SHOWN IN THE "FRONT VIEW" OF SHEET 2. CLEAN THE AREA WITH ISP ALCOHOL AS REQUIRED, WIPE DRY AND APPLY BY REMOVING ADHESIVE BACKING AND PRESS BUMPER NEXT TO THE PC ON/OF SWITCH.

REVISIONS AUTHORIZATIONS

REV	DCO	BY	DESCRIPTION	CHECKED	DATE	APPROVED	DATE
A	109075	QT	PRODUCTION INITIAL RELEASE				
B	01-0345	QT	REMOVE SCSI CARD # 2				
D	01-0692	QT	MOVE NIDAQ INSTALLATIN TO DWG 10798-004 CHANGE ORIENTATION OF FLOPPY DRIVE AND MO DRIVE.				





10X DETAIL A
SCALE: 5/1

SEE SEPARATE P/L

THIRD ANGLE PROJECTION

DO NOT SCALE DRAWING

UNLESS OTHERWISE SPECIFIED
ALL DIMENSIONS ARE IN INCHES, [ ] ARE IN MILLIMETERS PER ASME/ANSI Y14.5M
TOLERANCES ARE:

FRACTIONS	DECIMAL	METRIC
± 1/32	.X± 1	X± 1.5mm
	.XX± .01	X± 1mm
ANGLES	.XXX± .005	.XX± .05mm
±1°	.XXXX± 0005	.XXX± .005mm

VIEW SETS:
formation view: 10798_002_sht_1
view: 10798_002

DEBURR AND BREAK ALL SHARP EDGES

	DATE
TOLEDO	03-13-00
DESIGN: P. MYERS	03-13-00
CHECKED:	
APPROV. ENGR:	

LINKED 3D CAD FILE: 10798_pc_assy.pkg

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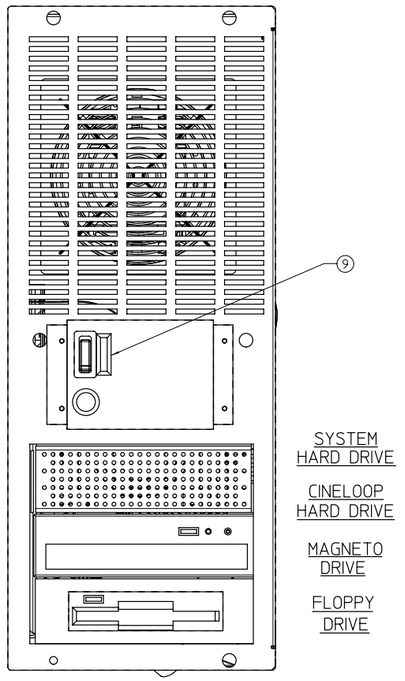
Boston Scientific
IVUS Technology Center

TITLE: ASSY, REAR PANEL, PC, GALAXY

SIZE	DOC TYPE:	DWG NO.	REV
D	---	10798-002	D

SCALE: 8/10 & NOTED | CAD FILE: 10798-002-D.MI | SHT 1 OF 2

CAD PLATFORM: ANNOTATOR



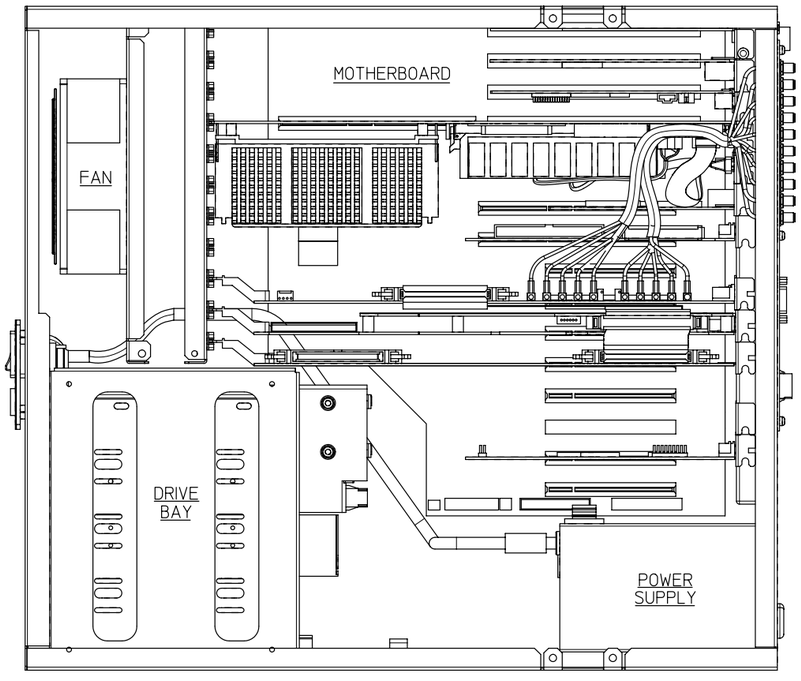
SYSTEM HARD DRIVE

CINELOOP HARD DRIVE

MAGNETO DRIVE

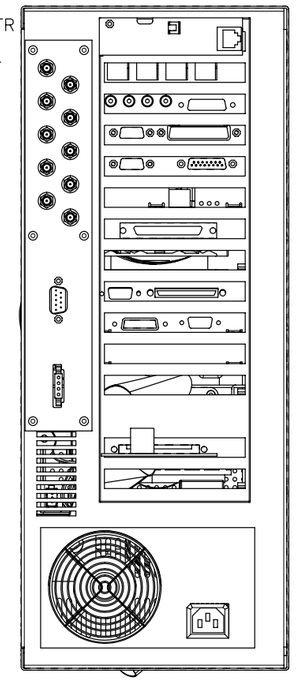
FLOPPY DRIVE

FRONT VIEW
(VIEW SHOWN UPSIDE DOWN)



TOP VIEW

ISA SLOT 3	N.I. -NI-DAQ. ADPTR
ISA SLOT 2	COMTROL SERIAL
ISA SLOT 1	SOUND BLASTER
CPU SLOT CPU	CPU
PCI SLOT 1	ETHERNET
PCI SLOT 2	SCSI #1
PCI SLOT 3	N/A
PCI SLOT 4	MERLIN
PCI SLOT 5	MATROX
PCI SLOT 6	PSC
PCI SLOT 7	N/A
PCI SLOT 8	N/A
PCI SLOT 9	PBUF
PCI SLOT 10	N/A



REAR VIEW
(VIEW SHOWN UPSIDE DOWN)

CAD PLATFORM ANNOTATOR

FORMAT NO. IVUS-0278-000 VER AA

Boston Scientific
IVUS Technology Center

TITLE: ASSY, REAR PANEL, PC, GALAXY

SIZE	DOC TYPE:	DWG NO.	REV
D	---	10798-002	D
SCALE: 6.5/10	CAD FILE: 10798-002-D.MI		SHT 2 OF 2